**Stroke SIG & JNPT Collaboration: Discussing the Clinical Practice Guideline for the Use of Ankle Foot Orthoses (AFOs) and Functional Electrical Stimulation Post Stroke Episode 14**

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**Hi, this is Pierce Boeing, the new digital media editor for the journal of neurologic physical therapy. I'm excited to welcome you to the second episode of author interviews from the Journal of Neurologic Physical Therapy performed by special interest groups of the Academy of Neurologic Physical Therapy (JNPT). In this new series, the ANPT's SIG podcast teams talk with JNPT authors about their research, unique and unexpected findings, and how to translate these findings to clinical practice. In this episode, the stroke SIG is interviewing Dr. Therese Johnston, Professor in the Department of Physical Therapy at Jefferson College of Rehabilitation Sciences, and Dr. Lisa Brown, Assistant Professor in the Department of Physical Therapy at Boston University. They will be discussing their article, A Clinical Practice Guideline for the Use of Ankle Foot Orthoses and Functional Electrical Stimulation Post Stroke, which will be in the April 2021 issue of JNPT. This is an exciting new guideline, since this topic tends to be a black box for clinicians. Thank you everyone for speaking with us today. Please introduce yourself and tell us a little bit more about your saw this podcast.**

Hi, my name is Lisa Brown, and I am a Clinical Assistant Professor in the Department of Physical Therapy and Athletic Training at Boston University. My experience with AFO's is in the clinical application of these devices in adults with neurologic disorders including stroke in both the inpatient rehab and outpatient settings.

So hi. I'm Therese Johnston, and while I was a Professor at Thomas Jefferson University while this CPG was being developed, I am currently Medical Director for the Division of Bracing Supports at Oesser, and so my experience with AFOs and FES is with children and adults with spinal cord injury and children with cerebral palsy. I've used different applications in those population in my research.

Thank you Dr.'s Brown and Johnston for speaking with us today. **The first question that I have for you is can you define the purpose of the CPG and the primary question that the CPG sought to answer.** Sure, the reason the clinical practice guideline was developed, as you had mentioned, was to provides some clinical decision making in this topic for use either for AFO or FES as an intervention to improve outcomes for individuals with post stroke hemiplegia. The clinical question that we defined in the CPG is if AFO or FES effective at improving outcomes for individuals with decreased lower extremity motor control due to post stroke hemiplegia.

**Can you next clarify why the CPG was developed?** The Academy of Neurologic Physical Therapy actually put a call out for development on this topic. The original ask was fairly broad, just on the topic of orthotics and neuro prosthetics. Initially, we considered multiple neurologic diagnoses, but after reviewing the literature it was apparent that AFO and FES was researched quite extensively in individuals post stroke, so we made the decision to narrow the topic population down to only include stroke. We did still want to address outcomes across the ICF domains, so we chose to keep the outcomes fairly broad as you'll see the guideline; This was in part to address concerns that had been brought up by clinicians and consumers. In the initial development stages of the CPG when we surveyed clinicians and consumers that used both AFOs and FES to better understand what the knowledge gaps were and what was identified from clinicians was that there was a need to have improved understanding of just the examination process, better understanding of the clinical decision making related to timing, potential impacts, and outcomes of application of AFOs and FES, and consumers had identified a need for more extensive education about device selection, use of devices, and the expense along with increased training prior to their final device selection. Both groups had identified a need for understanding the different effects that a device might have and what the long-term impacts might be on recovery.

**Next, I would like to clarify some terms. What is meant by 'improving motor control', 'hemiplegia', hemiparesis', and how are these impacted negatively or positively with AFOs/FES devices?** So initially we considered addressing only foot drop in this CPG, but as we read more literature and reflected on the reasons to select an AFO or FES clinically, it became clear to us that we needed a broader definition. So while most of the literature mainly addresses foot drop as the reason for an AFO or FES, it was important to understand the effect on stance phase stability and balance. Thus we felt that motor control was a better term to address the needs for this CPG.

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Then when looking at AFO and FES, we also need to keep in mind that a patient with very poor stability may not be able to use FES since FES only provides assistance during swing. So, clinically, we may choose an AFO and the specific type based on the patient's stance phase stability. That is, in this, our clinical decision making is critical based on the examination of our individual patients to make sure we addressing their unique needs.

**That makes sense, since how the with the people who had strokes present are very vast and since foot drop is part of it but there are things happening at the ankle and other joints that are more covered by the terms you discussed.**

**Is there a certain time frame post stroke that is presented in the CP? We chose to include all the times post stroke in our initial search?** We wanted to be comprehensive across the continuum of care for the population. As we read the literature we decided on our definitions of acute stroke being in the first three months, and chronic being three or more months post stroke. But we included everything in that chronic phase three months and however many years post stroke that the participants in the study were.

**Were /are there certain device types presented, does the CPG include the different types of AFOs and FES devices available and commonly used?** We included all relevant devices that were found across all of the studies that are included in the CPG. And what we did is we group them into categories by device type and so there will be a table in the CPG and people reading it can easily refer to the table. The CPG also provides definitions of these device types but in much of the literature the devices included were just described as a device that was designed to meet the needs of the individual. So, it made it difficult to identify exactly what device was provided in much of the literature and so because of this the clinical practice guidelines. Doesn’t go to the extent of making a recommendation about a specific device used to meet a specific type of goal, but instead we emphasize the need to include clinical decision making behind “What are the needs of the individual in front of you?”.

I think that's helpful, and I know for me, you think, “I want one CPG that is a specific algorithm. But it's really not going to be like that, so it seems like the CPG is more providing guidance rather than a specific answer for each patient. Right, exactly, and as you know, we understand that that's what people were looking for was problem ‘X’ will be solved by using this type of device, and you know, as we know with much of interventions for neurology is that it doesn't quite fit quite as neatly, and you really need to understand what's happening with the patient in front of you what their goals are, and what are the individual reasons why they're having the difficulty that they are.

Yes, it also really emphasizes the role that PT is have in this. Our expertise is critical in this, and I think that what really stood out in this is we [PTs] are important part of this process.

**Can you share with the audience how each action statement is organized within the action statement and how the ICF domains were used to categorize the action statements?** We felt that it was important to use the ICF framework, and that was an appropriate way to organize the action statements. As all of our statements really are focused on outcomes, and so you'll see in the CPG that it's organized starting with participation, an action statement related to a participation restrictions, and then ,action statements that are related to activities, and then statements that are related to impairments in body structure, and then from there within each action statements, you'll see that we have it further divided by acute and chronic; And this was because much of the literature that -at least the stronger literature -is focused on the chronic phases of stroke. And so, some of the recommendations might vary whether it's chronic or acute stage of stroke and so we did break the recommendations down that way. And lastly, we then break each statement down by the type of effect and the effect the device might have on you.

**Can you define what orthotic, immediate, combined, therapeutic, and training effect mean, and how you use each of these in each action statement.** So, understanding the distinction between these effects is really important when reading the CPGs as all of our outcomes are reported based on these effects. So, table six in the paper provides the definitions that we are using the CPG, and we do suggest that readers print this out and leave it out nearby, as they read the CPG. We did this ourselves as we were developing the CPG. We thought this was important to keep reflecting back on what these different out effects were. So, there are four different effects reported in here[the CPG]. So, the first one is an immediate orthotic effect. This effects is what occurs when we provide the patient with an AFO or FES and then immediately compare performance with and without it.

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The second effect is a therapeutic effect, and this effect occurs when we provide the AFO or FES as an intervention as part of the plan of care with the goal that the patient will have some Neurorecovery and not need the device anymore. In this, performance is assessed without the device before and after the period of intervention. And then we go to our third one, which is our training effect and this occurs when provide four FES is part of the plan of care to allow gains with the device on so with this effect. Performance is assessed with the device on before and after a period of intervention and then the last one is a combined orthotic effect and this one also occurs when we provide an AFO or FES as part of the plan of care to allow gains. What with the device on but for this effect, the performance is assessed with the device off before the intervention begins and then with the device on after the period of intervention. So, I understand these effects are confusing when you first hear them. And that's why we recommend that you print these out as you're reading the CPG. and keep going back to refresh your memory to make sure you are understanding what we're saying as we go through the CPG.

**That's definitely helpful. And i think these distinctions help everyone focus that the fact that we need to be more goal oriented in what we are trying to do getting somebody orthotic so I think when I read that it was really helpful to even realize there's such a division in these types of effects.**

**Can you describe the outcome measures that were assessed each ICF level**? In the appendix or table 1, we describe and lists the outcome measures and which tests and measures were included under each outcome. So, while many outcome measures may capture more than one construct we chose to group outcome measures within each action statement by the construct that it primarily defines, and so for example under the activities domain action statement 2 addresses gait speed. So, the outcome measures that were included in that action statement are only measures that assess speed of gait. So, the most commonly used assessment across this action statement was of course the ten-meter walk test. However, there are multiple studies that use tests of different distances. Like by feet or, you know, twenty meters to report this outcome. Then, for example, when we have action statement 6, which is under the body structure and function domain and addresses spasticity, measures that are included here. An example is the modified Ashworth Scale, where the primary construct that it's measuring is spasticity.

**Can you now briefly summarize what such how evidence level is defined evidence levels 1 through 5, and grade strength A through D, and P&R, and how that’s** **defined?** Tables one and two in the paper guided the assessment of the levels of evidence for the studies and the grades for the recommendations. These tables are actually from the APTA CPG manua that is available to all PTA members on the APTA website. We were fortunate to be involved in the development of this manual. So, if you look at table one in this CPG, here’s where levels of evidence are assigned based on the study type such as a randomized control trial (RCT). So that study is then assigned a number and a strong RCT would be assigned a ‘1’. Table 2 then provides guidelines for determining the overall grading of the actual recommendation, and these are graded as strong, moderate, or weak. To determine this grade for each action statement, we examined all the evidence for each action statement based on the benefits and harms and the preponderance of studies of different levels of evidence. For example, an action statement with a large number of level one studies that showed a clear benefit would be assigned a grade of strong. So, we went through this process for all studies and all actions statements to assign the proper levels of evidence and the proper grading for each of our recommendations.

**Now that our audience understands the development of the CPG. Today will be addressing two of the recommendations -we would like to focus on gait speed and muscle activation.**

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**Let's first discuss action statement 2. Action statement 2 is focused on the use of AFOs or FES devices to improve gait speed. The evidence quality is a 1 for all constructs excluding acute FES , which is 2, in individuals with chronic stroke and moderate for individuals with acute stroke. This construct is walking speed over a level surface and the reason this is important is because at increasing gait speed may increase mobility balanced confidence and health at any phase post stroke. We know walking speed is now considered the sixth vital sign. So does this mean we would want to consider am AFO to directly help with walking speed?, and that we would potentially want to start it in the acute phase in order to get people walking sooner and faster?** A**lso, does this mean. FES devices may be more beneficial during the acute phase potentially because neuro plasticity?** So, the short answer to this question is “yes”, that if an individual has a goal to improve gait speed which many will, then including an AFO or FES should be considered early in the rehab process. We can see from the literature that early application demonstrates that immediate and clinically meaningful effect in gait speed. If the AFO or FES is then included early as part of the plan of care, then the idea is that individuals may then be able to participate at a higher level of intensity, which then can produce more clinically meaningful benefits for that therapeutic or combined effects. Where the clinical decision making of the clinician needs to come in is which of these devices is going to best meet the needs of the individual. And so, for example, if the goal is for gait speed, what type of device will actually address this with the person that is in front of them? We also need to understand that the needs of the patient can likely change over time and so the device itself should also change over time. So, for example, if a device is applied at the beginning of an acute care stay, it may have that immediate effect of improving the individuals gait speed. They then can participate at a higher level and potentially improve more significantly by the end of their length of stay. At this point, maybe they need a different type of device to then further improve their gait speed or potentially just being part of the plan of care in the interventions that they participated in, maybe they won't need a device at all. There's evidence that both AFO and FES improve gait speed in the acute phase. There were only two level-2 RCTs that compared AFO to FES at this point; The first showed no difference between them, and the other that did show that FES had a greater increase in gait speed, but further research really is needed to determine if there is superiority of one device over the another.

**There is stronger evidence for AFOs in the chronic stages rather than the acute stages of stroke. Does this mean we should really be educating our patients about changing, renewing, or re-evaluating their AFO over time?** So, more studies have been done with AFO and FES in the population with chronic stroke. Especially when we look at FES. We really do need more studies that examine these outcomes after acute stroke but overall, what we can take away is that the studies that examine participants with chronic post stroke hemiplegia did show that gains can be made with both AFO and FES, and this finding indicates that routine re-evaluation is needed to allow people to continue to make gains and meet their goals. Thus, we need to educate patients and physical therapists about consistent re-evaluation in the chronic phase as the needs of individual often change. So, if PT’s can provide clinical evidence that the patient's needs are significantly different over time, a device modification or so a new device may be able to be justified.

**Many insurances will cover one orthotic only during a certain timeframe. How do you suggest clinicians navigate this?** So, we really emphasize the importance of strong documentation. This documentation is critical regarding the impact on outcomes and quality of life. The measures that we used in the CPG are important to the assess as well as key examinations that the PT feels are important for the decision making for that particular patient, and one consideration is the potential modifiability of the device over time if there are insurance restrictions, so that adaptations can be made as the individual changes over time. **Just to clarify there are devices that could start off as one type and be modified to a different type.**

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Yeah, I think you can modify for example a solid device into an articulating AFO type of device. You can modify a trim line on the AFO, so if at the start of care an individual needs more stability and support and they have more of a solid type of AFO with a trim line that's more anterior malleoli but then as they're gaining in ability and need less support, you can modify those trim lines and cut back. So, I think this is where it can be really important to have that relationship with the orthotist to understand what is the modifiability of the device itself and to have an understanding of your expectation of how the patient may change over time so that you can have that longevity – you onow is thye device going to meet the needs of the individual as they are improve.

**That's really helpful for clinicians to know. How can we help patients understand that braces like AFO's and FES devices are tool to help the patient especially when they can be cumbersome** **to depend on?** I think this is where it's again emphasizing the point that it's really important to bring it back to what are the goals of the patient, and so if they're coming to you, we can use that example again of gait speed that they want to be able to improve their ability to you know ambulate in their home or their community. We can address how or educate the individual about how one of these types of devices may be able to assist them doing it. Consistently including patients in the decision making process will improve their buy in as well as use of the device. You know we understand that promoting patient autonomy is critical for motor learning. And this really isn't any different. So if we're addressing the goals of the individual, educating the patient, as well as providing options, this is really important; And bringing it back to their particular goals. Then it likely will improve outcomes and compliance over time.

**Let's clarify what baseline gait speed is in assisting clinicians choosing a device and what is meant by adequate dosing?** So, the literature doesn't direct us based on baseline gait speed, so most individuals in the studies that were included in the CPG were ambulatory to some degree to be included in studies but we couldn't differentiate based on gait speed instead going back to the patient's goals and the clinical decision making of the physical therapists really are needed to decide what the best devices for the individual. As we read the literature, it became clear that more research is needed with dosing. But we did find that with PT intervention, outcomes were significantly improved. While an immediate effect can be demonstrated -so just assessing the individual without a device and then with a device in the moment the therapeutic combined backs that included skilled PT intervention further optimized outcomes and clinically meaningful improvements.

**Now let's review action statements 7, which discusses the effect of AFOs and FES devices on muscle activation. It is exciting that the CPG gets into the specifics of this since there's concern whether or not braces can limit muscle activation. As we know as clinicians, time since injury can dictate whether or not muscle activation at the ankle or knee is a feasible goal. The action statement reads as follows: “Action Statement 7: Clinicians may provide an AFO with decrease stiffness for individuals with decreased lower extremity motor control due to acute or chronic post stroke hemiplegia who have goals to allow activation of the anterior tibialis and gastrocnemius / Soleus muscles while walking with an AFO. Clinicians should provide FES devices for individuals with decreased lower extremity motor control due to acute or chronic post stroke hemiplegia who have goals to improve activation of the anterior tibialis and gastrocnemius/ soleus muscles while walking with an AFO. Clinicians should provide FES devices for individuals with decreased lower extremity motor control due to chronic post stroke hemiplegia who have goals to improve activation of the anterior tibialis muscle while walking around without FES. Acute AFO evidence quality level 2, recommendation strength moderate. Chronic AFO evidence quality level 3, recommendation strength week. So, in the first part of the action statement. It asserts clinicians may provide an AFO with decreased stiffness while in the second part it says clinicians should provide an FES device. How should clinicians interpret this distinction?** So, it should first be noted that the evidence for muscle activation, the statement is weaker than for other actions statements.

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So, the main recommendations that come into play. The evidence was stronger for acute than for chronic stroke, and a couple of variants stood out to us in the action statement. This was the only action statement in which we could make a differentiation based on device properties for both the acute and chronic phases. Increased muscle activation could be achieved whether the AFO was less stiff and following acute stroke, this may allow the patient the opportunity to activate muscles such as the dorsiflexors during walking if that muscle can be activated by the person. While the evidence does not link this activation to recovery, opportunities to activate volitional muscles while walking is a goal in early rehabilitation. For the chronic phase, continuing to allow opportunities for weakened muscles to be activated while walking may keep that muscle active. We realized that some patients may require stiffer AFO for stance phase control or with absent dorsiflexion activation again. Again, our clinical decision making becomes really important for each patient based on the individual needs. And when looking at FES, the research is focused on the chronic phase. So, that's why this action statement only includes the chronic and provides that strength of recommendation. The evidence is strong for a therapeutic effect even in this chronic phase stroke, and what’s good about this is that these studies are showing that gains are possible for patients longer after stroke, which reinforces our recommendation to have routine re-evaluations of patients because people can continue to make gains. **This is definitely really helpful for a clinician to know as for clinicians to share with their patients.**

**Can you describe what type of AFO would be an example of one with decrease stiffness? So, an AFO with decreased stiffness will be one made of materials that flex more.** So, this increased flex can come from the materials actually chosen as well as the trim line. So, Lisa mentioned that you can start with an AFO that has more anterior trim lines and trim these back over time and that's going allow more flex into that AFO. So, one that we commonly think of as being more flexible is a to release spring AFO, you can easily bend these in. So, this is typically a more flexible design, and the design they have to provide the stiffness for each patient should be discussed in conjunction with an orthotist as well as if an off the shelf devices is not meeting the patient's particular needs.

**This section further asserts that for a patient with an acute stroke, AFO's have moderate evidence for immediate orthotic and therapeutic effects for increased muscle activation with an AFO with decreased stiffness compared to one with greater stiffness. Can you explain what this means and what readers can take away from this clinically**? **The CPG asserts that for patients with chronic stroke, there are significant therapeutic effects of FES. How do we use this information to figure out what patient presentation or patient goals would make FES appropriate?** So, the decision regarding an AFO and FES really should be made between the PT and the patient, and the orthotist when needed. Many patients do prefer FES over AFO in the chronic phase when provided with that opportunity. I think we need to keep an open mind that our patients may still have the potential for gains. More research is needed though to identify the factors that would suggest who would do best with FES. As already mentioned, it is important that the PT consider the effect of stance phase stability if considering the FES as FES is only active during the swing phase, a patient with poor stability may need an AFO. **A knowledge translation task force has been created for this CPG. So, we have more to look forward to.** **Can you tell us more about this [CPG KT task force]? And what resources we should expect from this[CPG KT Task force]?** The knowledge translation task force has been working hard with us for quite a while. They have some educational resources that they're developing to support the CPG. There'll be a summary reference document that will be posted on the ANPT website right around the same time that the CPG is published. They're also in the very early stages of developing other resources such as learning online modules, so definitely keep your eyes on the lookout [for these]. There will be more to come. **Awesome, do you have any tips for readers of the CPG on reading it?** So, we understand that this document can be pretty significant to try to digest in one sitting. So, we suggest reading the action statement summary table first and then getting familiar with the effects. As Therese had mentioned earlier, we certainly would recommend having that table that defines the effects handy as you're reading it so you can refer to it.

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The tables on devices and outcome measures used could also be helpful. From there, readers can choose an action profile for an outcome of interest. So, for example the action statement 2 on gait speed. We realize that there is a lot in these sections so reading each action statement profile summary can provide some good information, and then at the end of each action statement we also provide a section called clinical interpretation that provides the take home message for clinicians. **There's so much information in this CPG. I hope readers will take a look at these indications as we only have time to skim the surface. However, I hope our listeners can better appreciate how to interpret and utilize the CPG in their practice.** There is also information about what our patients want and how to assist them with AFO /FES in their recovery. A summary of all action statements is also complete and found in table 3.

**Thank you everyone for taking your time to speak with us today to help our listeners further understand this new CPG. It was a pleasure talking with you both**. Thank you for having us. **Listeners, thanks for tuning it. And keep following us on ANPT synapse or google podcasts or wherever you get good podcasts for more episodes**.

Add-on material in the podcast:

Thank you for those of you who have stuck around this long. We wanted to share something special. It's a portion of the interview that we thought was quite interesting. I think it really demonstrates the challenges and the utility of the CPG in context of care in an unscripted portion of the conversation after the formal interview. So enjoy.

**I read it and i definitely did not break it down correctly in house reading it.** We literally would have it on the table and up on the wall and in my office. I have it in my office. You know, looking at itand having the visual. You know, that is really helpful to have that picture in your head of what you know what you're reading and how to interpret it . That makes a big difference. Yeah because everybody came to where I worked a few times, and we would just take over the conference room. We have all these giant posted things all over the walls and the effects of the big one that we would look at it -so dense in a good way -early on. Reading it is… you really have to focus in on what's being said. But I imagine creating and looks like because it's yours. We debated on how to divide this out, and we felt really strongly that breaking down these effects was really important. Because I think, especially for a patient who you prescribe and AFO. You give it to the person and you have that immediate effect of greater and better, and then there might not be any follow up, right?! So, they are sent home with the device and so I think it is important to understand that, okay, even though they are better in the moment... Then, if you're including an intervention- a skilled intervention focused on the individual working with a brace at the -working at a higher level, the outcomes are then even more significant regardless of whether it's an acute or chronic stage of stroke. So, i'm hoping that people do truly understand what the different effects are and get that clinical interpretation piece that you really have to think of “how are you applying it?”. Do you want to just apply it as an intervention? So, I'm only going to use this during training or do I need the person to be really safe right now. Because they're going home, and you know their spouse can't help them and you know… or “am I going to have a period of time with this person where we can train for a longer period of time and really wait to make a final determination on what they need?”. We really need to be advocates for saying that this intervention period is critical.

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That it's not just about an AFO, that we have to stand up and say, “No!”. This patient needs this- this many weeks of intervention because the patient can make so many more gains and I know that doesn't happen a lot and you know something that we as PTs can try to push for. I think with the amount of research that's coming up on high intensity training, the use of AFOs as a treatment effect can be really helpful This even helped me thinking about trying to train to not use AFO but this [patient’s] foot definitely gets away during the high intensity gait training. So, it could be good for us to use AFO so he can hit that heart rate during that specific intervention but not other interventions. That's really helpful with making sure interventions are focused. Because I think we could even make it better by adding FES. I mean, adding muscle may actually be increasing the intensity more. it's really a decision based on presentation. How complex do you want to get with everything and what the patient who wants. You may have a patient who says, I don't want a brace but I am willing to try FES or vice versa. **I know my site doesn't have an FES device. But I think we talked about a couple of times to have one as treatment device. But I know my Regional Director loves solid evidence of why we need something, and the outcomes that could come about. So, that's very helpful.** Great, FES and the therapeutic effects evidence is actually stronger than that for AFOs. So that's something to consider.