Talking Sleep Season 4
Episode 10
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Rajasi Mills, Guest

Episode Transcript

DR. KHOSLA: Thank you for joining us for Talking Sleep, a podcast of the American Academy of Sleep Medicine. I'm your host, Dr. Seema Khosla, medical director of the North Dakota Center for Sleep in Fargo.

With all of the new developments in consumer sleep technology, our patients are spending billions each year on everything from wearables to mattresses to help them sleep better. To talk to us today is Rajasi Mills. She's an engineer with a degree in medical devices and vice president of Sleep IQ Health and Research for Sleep Number. She is here to discuss the technology behind smart beds. For full disclosure, we're going to chat about the technology in general without focusing on the brand name. Thanks for joining us today, Raj.

RAJ MILLS: Thank you for having me.

DR. KHOSLA: So tell me about this. Tell me about Sleep IQ and smart bed technology. I mean, what is this in general sense? So not necessarily about your specific product, but what are these smart beds all about?

MILLS: Sure. You know, most of the technology around this area is really comprised of three components: the sensing, adjustability, and digital engagement. And so, you know, from a sensing standpoint, sensing component, there are variations of sensing components. Most common in the smart bed technology is ballistocardiograph and the ballistocardiograph, depending on the application, will take sample readings, you know, could be up to several hundred times per second And these readings will represent heartbeat and breath rate.
And you know, the application then uses the heartbeat and breath rates to calculate things like HRV and you know, and other sleep metrics like total sleep time, SOL, WASO and even exits out of the bed.

DR. KHOSLA: There was a paper that was published that talked about bed derived sleep stages, comparing it to PSG. So tell me about this.

MILLS: Sure, we'll do. There was a paper that was published in Sensors that compared the accuracy of a smart bed from a heart rate, breath rate, and the sleep metrics that I just mentioned to PSG, measured it against PSG. And what it showed was the heart rate and breath rate were highly, highly correlated, you know, .94, .96, which is very high considering 1 is the is absolute correlation with PSG. And you know, it, it captured you know, it really leads to this idea that we can think about using a consumer product at home to evaluate our sleep and evaluate it at a, you know, accuracy level that is, you know, maybe not 100% PSG. I don't think that will, you know, that will happen in the near future, but it's enough of an indication to really provide insights into sleepers’ health and sleepers’ just, you know, physiological activity.

DR. KHOSLA: So this is something that I kind of struggle with as a sleep clinician because, you know, patients are always asking me what should I buy? Right. And so I have a little bit like I try to be very respectful of, you know, not asking somebody to spend a lot of money on something. And so how should I be thinking of this? I mean, how does a smart bed compare to other easily accessible sleep technology like wearables? Or apps or other nearabled? I mean, how how should I wrap my brain around this?

MILLS: Yeah, that's a great question and I completely understand the decision. Right. And I think one of the biggest differentiators between other forms of sensing like wearables and nearables is that the bed is actually helping to improve sleep. So the smart bed, you know, has the capabilities of sensing, of providing the similar type of metrics that a wearable would have, but it actually, you know, through different adjustability components and through just the comfort of the bed is able to impact quality sleep. And I think that's the biggest differentiator.
**DR. KHOSLA:** So you're talking about something more than, you know, like raising the head of the bed to help with snoring, right?

**MILLS:** Yes. So, you know, there are smart beds in the market where the firmness can be adjusted on a nightly basis. So, for instance, I know, you know, I have a bad back and there are times where my back is acting up and the ability to change firmness is really important and really makes a difference in my sleep during those, you know, type those nights that my back is hurting. Or, you know, is for those who are pregnant or as we age, there is you know, there's needs and situations in our lives where we may want a slightly firmer bed or a softer bed. So that idea of being able to create those adjustments and create that perfect individualized solution for that night really is profound and helps with the quality of sleep.

**DR. KHOSLA:** So do you think that this will allow us to have more of a longitudinal assessment of sleep? You know, I'm hearing what you're saying about the back end pregnancy and aging and so on and so forth. And and I'm wondering, you know, if so, how will we use this information in a positive way for our patients?

**MILLS:** Absolutely. You know, first and foremost, that longitudinal nature, it provides, you know, so many beneficial aspects. Number one, it provides a view into a sleeper’s individual characteristics and baseline. Not every sleeper is the same. And so, you know, knowing your you know, your standard heart rate or your, you know, which setting provides you the best sleep night at night after night, it allows you to individualize your sleep. You know, again, I'll give you I'll use myself as an example, an example throughout this discussion. But I also, you know, sleep with my head slightly articulated. And that's just because as an individual, I know that that alleviates a lot of things for me, like propensity to snore or, you know, that's just for me, I have found my ideal articulate articulation angle. And so I'm able to do that because of the longitudinal nature of the data shows me where I, you know, what are the settings that give me my best sleep. And then over time, you know, we have conducted studies through longitudinal analysis of data that shows, you know, when I might be getting sick because my heart rate and
breathing rate and duration and motion of, you know, when I sleep, they are trending differently than my normal.

**DR. KHOSLA:** So that's really interesting that you bring it back to health. You know, I'm trying to think about is this something that we can use for people who have sleep disorders? You know, that's always been a criticism of sleep technology, that it's always tested in healthy people and how do they perform with people who have sleep disorders. So is this something that will help us maybe look for sleep disorders?

**MILLS:** Yes. And I would say that, you know, most smart beds, I would say really other than hospital beds, smart beds that are used in the home are consumer products, so they're not medical devices. However, we also know that there is such a large prevalence of undiagnosed apnea, undiagnosed cardiovascular health factors that we are able to find and not only find, but just early, you know, find early indications of situations like apnea where we can warn or we can, you know, provide insights to our sleepers to then go and get the a diagnosis or, you know, go get tested. And I think that really is a gap between that early indication, you know, where your apnea may be at a mild level or even moderate level. And so having that early diagnosis can maybe even prevent it, prevent that sleeper from getting to, you know, a more advanced stages of whether it's apnea or other health factors.

**DR. KHOSLA:** OK, so that's interesting. You know, when you talked about comparing it to polysomnography, then in my mind, of course, I go through, well, why do we order polysomnography? Typically, we're looking for a sleep disorder, right? And so now you're kind of talking about early screening and early identification then. But just to be really, really clear, you're you are drawing a line where you're saying this is a consumer device and this is not meant to go into that diagnostic realm. Correct? Am I understanding that correctly?

**MILLS:** That's right. That's absolutely right. You know, the metrics that we collect you know, heart rate, breath rate are very highly correlate with PSG, as I mentioned. And those indicators or the, you know, those signals and metrics, they will help us, they will help the sleeper, they will help us help the sleeper identify those elements that, you know, really do need to be tested on
PSG. A PSG is a, you know, FDA approved device for diagnostic. The smart bed is a, you know, consumer device that helps bridge the gap between health indications at home to the clinical environment. And we're really seeing this in so many areas of health today where health systems are trying to move to the home because because of that preventative aspect and, you know, as you as, you know, catching something early. Right. You know, preventing it just lowers that cost burden that we face today.

**DR. KHOSLA:** So when you're talking about following trends and assessing that there's a change in heart rate or respiratory rate or something like that, or that there might be a risk of a sleep disorder, how is that then communicated to the patient? Is it something that they can print out and take to their doctor? Like, what does that piece look like?

**MILLS:** Yes, absolutely. So I would say that there are varying levels of insight. You know, today we are able to see trends in your heart rate and breath rates and, you know, the different biometrics that we capture. And we have had scenarios where our sleepers have contacted us saying that they noticed a trend in their you know, in their data and they took that information to their physician. And, you know, it resulted in, you know, there's one particular case where it resulted in some surgical procedures. So, you know, but even in what we provide, we provide weekly and monthly trend reports that are sent, you know, available for the sleeper to access through their mobile application and we also send them through their through email. But they can take that information that really, you know, points out the differences over the months in their data, how they're trending in those specific categories, and take that to their doctor. And, you know, time and time again, we have heard different people having done that, having taken that information to their doctor and really you know, it producing some kind of, you know, some action that saved their life.

**DR. KHOSLA:** So is it something that they then you alert them that this is what your heart rate has been doing over the last 30 days? And is it up to them then to sort of say, oh, that's a change? I mean, do you do you put in anything about this may be consistent with or, you know, or is it sort of up to them to just say, OK, this is a change, I need to go to my doctor?
MILLS: So, you know, we don't because we are not a medical device. We don't provide that that we don't close the gap. You know, we don't make that connection and we're not their doctor. You know, it's really up to their doctor to take the data that we're providing and then you know, kind of marry that with their other health records to provide the determination of what their actual, you know, health condition could be. But so, you know, but what we provide is that view that then can be used to make that analysis a view that the doctor might not have. And certainly most of the time, you go visit a doctor, it's once a year or when you're already have symptoms for something other than your farther along in your condition.

DR. KHOSLA: So it'll allow you then to provide it like a record. You know, I see people with Fitbit and you know, whatnot in clinic, and I'll scroll through it and say, look a look at their sleep and see if we can correlated to their symptoms. But that's also very, very specific because it's a sleep clinic, right, versus sort of this general, my heart rate is varying or respirations are varying. And so and so I appreciate that it's looking at that data plus the clinical symptoms to decide if something needs to be done.

MILLS: That's right. And you know, this this will you know, progress. So in the future, like I mentioned, we are going to you know, we're looking at developing further analysis around the early risk indicators for things like apnea and cardiac health. And we're doing that with our partners and our collaborators and so, you know, this is a progressive, this technology allows for progressive results and progressive path for us. Today it's the trends in in the raw data of heart, you know, heart rate and breath rate, and HRV. HRV is another important calculation that, you know, where the HRV trend can be telling about someone's health.

DR. KHOSLA: Hmm. So, you know, you kind of hinted at this earlier, but I'm kind of wondering how this performed during this pandemic. Were there signals that you saw? Were you able to identify people that maybe were at risk of getting sick?

MILLS: Yes, that is a great question. And I would love to share this information because it's so fascinating. But in 2020 you know, right in the thick of the pandemic we conducted an IRB-approved study where we solicited information from sleepers who had opted in to be part of a
research panel. And we identified cohorts of COVID-19 positive and negative sleepers. And the analysis of the real world sleep data that were that was collected that, you know, included things like that. I mentioned with the heart rate, breathing rate, motion duration, time to fall asleep, all of those, you know, metrics were collected in that this unobtrusive environment in the sleepers own home. And they were collected around the time that the sleepers had had mentioned to us or had had disclosed that they either were tested positive or negative or that they had symptoms.

Oh, yeah. And just fascinating. And we saw a stark difference in the trend of their data. You know, if you compare their data two weeks prior to symptoms, and, you know, during symptoms there, you know, we are able to see in the data even before many of the sleepers actually experience those symptoms, we're able to detect in their sleep data a shift that was pretty staggering. And the other interesting thing is that because, you know, the data is longitudinal, as we as we talked about earlier, we were able to compare the data around this COVID time period with even the prior year of the same sleeper. So, you know, the sleeper was became their own control. It was just fascinating to to see that data.

**DR. KHOSLA:** So let's take a quick break. And when we come back, we'll talk about the relationship between sleep and other health issues. You're listening to Talking Sleep from the American Academy of Sleep Medicine.

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**DR. KHOSLA:** Welcome back to Talking Sleep. Today's guest is Raj Mills, a medical engineer at Sleep Number. So, I understand that Sleep Number has undertaken some really interesting partnerships to support sleep research. So can you tell me about your collaboration with the American Cancer Society and the Mayo Clinic?

**MILLS:** Happy to. Earlier this year, Sleep Number entered into it’s a six-year partnership with the American Cancer Society and the intent is really to inform cancer specific guidelines. And, you know, the American Cancer Society will consent Sleep Number sleepers in a prospective cancer prevention study to identify the impact of quality sleep on cancer prevention and
recovery. And really for both patients and survivors, because we know it takes a toll. Sleep really impacts both the patients and their caregivers and survivors. So it's a really important study and of an area that is not has not been highly studied by the American Cancer Society to date.

And in addition to that Sleep Number is also collaborating with the Mayo Clinic as you mentioned. And in that collaboration, we are advancing we're working together to advance sleep science and research. And a couple of examples I'll give you of studies that we're working on together or funding. You know, the Mayo is investigating the prevalence of OSA and determining the presence of comorbid cardiovascular diseases in U.S. patients with Somali heritage. It's a really unique study and this this group of you know, this group, this specific group has not researched very you know, there's there isn't a lot of research among this group. And another study that the Mayo is you know, we're also working on, is the relationship between disrupted sleep, disrupted sleep and markers of aging. So very, very just interesting, groundbreaking work.

**DR. KHOSLA:** Wow. That's kind of amazing, isn't it?

**MILLS:** Absolutely. It is. It's amazing how much insight sleep and our sleep data and our bodies can tell us about our overall health in, you know, it from from sleep.

**DR. KHOSLA:** Well, that's exactly right. Intersect intersects everything. Everybody needs to sleep.

**MILLS:** Yes.

**DR. KHOSLA:** So what about the other side? If I'm thinking about this connected bed. So are there any warnings or precautions? I mean, you know, there are on some of the gadgets that I have, there's a little sticker that warns me about low dose electromagnetic radiation. So is this something I need to worry about or maintenance or anything like that?

**MILLS:** You know, the the products at Sleep Number, the bed smart beds are all tested out for, you know, SAR, we call that SAR, specific absorption rate test. And they're all tested by
independent agencies, and we're certified as compliant to FCC standards. So, you know, we take that very seriously. And, you know, there's not, we don't have the same level of contact with the sensors because the sensors are all embedded in the bed, as with maybe other devices that directly touch the skin. But, you know, absolutely, you know, safety is extremely important as I mentioned, we are we continue to test, you know, with every new innovation that we that we have. And, you know, we're again, we we take that very seriously.

**DR. KHOSLA:** So what about data security? I mean, where does a data live? That is from a smart bed.

**MILLS:** Yes. Another area that we take very seriously and especially when you think about, you know, your sleeping environment is a very personal environment. And, you know, our data security and privacy are all crucial to that. And, you know, the data the data resides both in the bed, there's a pump by the bed, so it temporarily resides in the pump, but then also in the cloud. But users have the ability to put their bed in privacy mode, in which case we collect absolutely no data and that is a very strong approach we have, you know, we like I said, literally, we collect no data if it's in privacy mode. But even if it's not in privacy mode and we're collecting data, we, you know, again, have very extensive you know, implementation of different levels of encryption and just different safeguards in place to make sure that the data is, you know, just secure and only available for the sleeper.

**DR. KHOSLA:** So what about looking at the data collectively? You know, I'm thinking back to a few years ago when Fitbit released I want to say maybe 6 billion nights worth of data. And from that they said, well, you know, on average, females sleep a little bit more than males. And they kind of showed like the variation in bedtime depending on your city. And it was it was just a really interesting batch of information. So I'm wondering if you can, you know, is this something that's on your radar? Are you looking at this?

**MILLS:** Yeah, absolutely. And, you know, because we, like Fitbit, we're able to assess data from a regional and other population-level views. And in fact, also at SLEEP 2021, we presented an overnight HRV metrics and values for a large population. And that was to better understand
population-level HRV changes and we did that over, I want to say, almost 380 or so thousand men and women. And we are continuing to look at, you know, our de-identified data set for that population level analysis and I would say to your listeners, stay tuned because we're continuing that work, it's ongoing and you know, we are you know, we have plans to share our analysis at future conferences and certainly looking at different publications as well.

**DR. KHOSLA:** So speaking of, you know, Charlotte is in a couple of weeks are you, I understand you're presenting. What are you talking about?

**MILLS:** Yes, absolutely. We're so excited about Charlotte and SLEEP. We're going to be sharing two presentations, one in which we utilize a two-process or TPM model for sleep regulations. And, you know, a lot of your listeners may know that already. And this TPM model, as you as you know, has been used to characterize subjective alertness variations throughout the day. But, you know, what we've seen is that the evidence that supports the TPM-derived alertness has been mostly from small scale controlled studies. And so what we're showing is that alertness measures can scale to large study samples under these real world conditions. So really, you know, taking what is, what science has already shown us, but applying that at a large scale.

**DR. KHOSLA:** Oh, interesting.

**MILLS:** And then this second study will present, we'll discuss an aim to estimate, distal skin temperature unobtrusively during sleep. And again, with sensors that don't touch the skin itself. But, you know, using a temperature array under the mattress. And with that, we're able to approximate both distal skin temperature and the microclimate temperature. So we'll share our algorithms in doing that.

**DR. KHOSLA:** So what can you tell from distal skin temperature?

**MILLS:** So we're able to you know, this the application of this first round of temperature sensors will be in our Climate 360 Smart Bed, which is a bed that not only has the temperature sensing but is has full body cooling and heating. And as you know you know temperature is so key and just instrumental to our sleep and the fluctuation of temperature you know not only the
temperature fluctuate throughout sleep. But as we age you know we go through different temperature needs and changes you know menopause and different people need different cooling mechanisms that really disrupt and temperatures can be very disruptive to our sleep. So being able to measure the temperature will allow us to adjust the temperature to be able to keep someone asleep throughout the night.

**DR. KHOSLA:** Oh, see, I was thinking of it in terms of more core body temperature and the drop of core body temperature and its association with sleep onset. But you're approaching it more from a sort of improving sleep by looking at yet another metric, right?

**MILLS:** Yes, that's right. And, you know, we have insight into we can have kind of insight into core body temperature through these other mechanisms or, you know, by measuring the changes in skin temperature as well as the microclimate temperature can give us, you know, a view into what the core body temperature might be.

**DR. KHOSLA:** So is there anything else that we should know about this technology?

**MILLS:** Well, I mean, it is it is just such a fascinating area. But, you know, I think this technology I would say it just it not only provides insight and the ability to improve sleep, as we mentioned, but in the future, we also talked about this, it can be used to provide that early risk indication of health and, you know, just broader health factors and you know, that in itself really is a game changer.

**DR. KHOSLA:** Hmm. So any final thoughts.

**MILLS:** I well, first of all, really love your overall podcasts. I have listened to many of your shows. So a big fan and I would say so happy to be here and share this technology. It is really groundbreaking. And it is not you know, it's it's well understood by our team but not, you know, not as well understood by the broader community. And, you know, the power of this technology is why we're seeing, you know, just groundbreaking and organizations like Mayo Clinic, like American Cancer Society and several others that will announce in the future, why these organizations want to work with us because of the power of this technology.
DR. KHOSLA: You know, and it's something that I think I've learned to appreciate about our sleep community. You know, the AASM a few years ago came up with this technology committee and it's had I don't know how many iterations with different names, but it's basically looking at. looking at consumer and clinical sleep technology and developing sort of this resource for clinicians where you can understand what the technology is and what is the objective data supporting it. Not like a, a Yelp or like a I like this bed type of thing or I like this app or I like this watch, but just really being objective and saying well, what is it measuring? How is it measuring? What are the sensors, what is the data? And so I appreciate, you know, who I'm sure Steve Van Hout but whoever came up with considering this and this has been years now, so I love that they are making it more understandable to your point that you understand it, but how do you translate that so that we understand it and help our patients to make that decision? Of is it worth it for them? You know, what is it going to tell us? Where does that data go? Is there something we should worry about? So I appreciate that.

MILLS: Well, I think that is fabulous because, you know, I mean, ultimately, people sleep at home and they're in their houses, right. And the more insight that we can provide to this sleep, the clinical, you know, users or the, you know, the clinical caregivers of the sleepers in, you know, more insight from the sleepers’ homes, the better that the treat the treatment can be.

DR. KHOSLA: Well, thank you for talking with us today. It really is amazing how much sleep technology has advanced even over the last few years to help us better study and improve our sleep.

MILLS: The pleasure is mine.

DR. KHOSLA: Thanks for listening to Talking Sleep, brought to you by the American Academy of Sleep Medicine. For more podcast episodes, please visit our website at aasm.org. You can also subscribe through your favorite podcast service. And if you enjoyed this episode, please take a moment to leave a rating or review. For more feedback or suggestions email us at podcast@aasm.org. I hope you'll join us again for more Talking Sleep. Until next time this is Seema Khosla, encouraging you to sleep well so you can live well.