

1 San Diego, California Saturday June 21, 2014

2 --oOo--

3 CHAR: Good morning.

4 (Audience responds with "Good morning.")

5 CHAR: Come on, good morning.

6 (Audience responds louder with "Good morning.")

7 CHAR: Much better. Thank you, thank you.

8 It's going to be hot today. It's going to
9 be in the 90s. So we're lucky that we have
10 air-conditioning, and Linda, we're so happy to
11 see you. You've been missed.

12 Marilyn's not here today and Corrine's not
13 here today. So anyway, I'm very excited about
14 this presentation because we've never had one
15 on the hybrid cochlear implant. How many even
16 know what that is, a hybrid cochlear implant?
17 Just hardly anybody, right?

18 And the Baha? How many of you have heard
19 of the Baha? Oh, a lot.

20 So two totally different things. We've
21 had presentations on cochlear implants and
22 hearing aids, but we've never had it on these
23 two. Maybe a Baha once. I can't remember.

24 Anyway, I think we're just running a
25 little late so we'll start right off. We have

1 a few new members in our group, which we're so
2 happy to see them, and is anyone willing to
3 stand up and introduce themselves? First time?

4 AUDIENCE MEMBER: Hi, good morning. My
5 name is Alice Kendall, and I used to be an old,
6 old member when it was self help. So I'm glad
7 to come to the meetings. Thank you.

8 CHAR: That reminds me of a funny story.
9 Self help for hard of hearing. I've told this
10 before, but I was new to the whole support
11 group and I never heard anybody say that. I
12 was S-H-H-H. So I was at my audiologist today
13 and I said have you ever heard of, "Shhh?" I
14 said "Shhh." I thought how you pronounced it
15 was "Shhh." They thought I was a little nutty.
16 Anyway, that's how naive I was.

17 Great to have you here. And?

18 AUDIENCE MEMBER: Hi, everybody. My name
19 is Jackie. I was here once before at Christmas
20 and back again to hear about the Baha. Glad to
21 be here.

22 CHAR: You're interested in the Baha?

23 JACKIE: I'm single sided.

24 CHAR: She's single-sided deafness.

25 And Ginny, may I ask you to stand up and

1 introduce yourself?

2 AUDIENCE MEMBER: Hi, I'm Ginny and I'm
3 from up in San Marcos, and my first time. So
4 I'm glad to be here. My doctor recommended
5 that I come.

6 CHAR: Let's give a hand to her doctor.
7 That is just awesome.

8 Let's go ahead and introduce -- First of
9 all, for the new people, you know, we're an
10 organization that provides support to people
11 with hearing loss. We're a family. We have
12 lots of fun. We have speakers, and we like to
13 share the newest and greatest to help you hear
14 better, along with coping mechanisms. And
15 what's really going to be interesting, I just
16 want to bring it up, is next month, July, it's
17 going to be Dr. Allison Freeman. She's a
18 clinical psychologist and she's going to be
19 presenting on navigating a successful --

20 AUDIENCE MEMBER: That's the wrong
21 speaker.

22 DOLLI: It's going to be an audiologist.

23 AUDIENCE MEMBER: It's Dr. Providence
24 Alvira. Dr. Providence Alvira, she's an
25 audiologist.

1 CHAR: Are we going to have the
2 relationship one? Did that person just drop
3 out?

4 DOLLI: Marilyn asked that person not to
5 speak because this had been planned beforehand.

6 CHAR: Oh, I see.

7 Without further ado, Erin Levy and Maeve
8 Browne of Cochlear America. They will be
9 discussing the hybrid implant and Baha
10 technology. That's kind of a sexy name.

11 Come on up. Give them a hand.

12 (Applause.)

13 ERIN: My name is Erin Levy. I'm an
14 audiologist that works for Cochlear here in
15 San Diego. I live in Oceanside, and I've been
16 an audiologist working with deaf and hard of
17 hearing patients for 14 years, and I'm very
18 open to any questions. So at the end of the
19 presentation, please feel free to ask
20 questions, or if you're too shy to do that,
21 please just catch me afterwards.

22 First I'm just going to talk a little bit
23 about understanding your hearing loss. Many of
24 you probably already know about your particular
25 hearing loss, but it's always nice to have some

1 of this stuff repeated.

2 So one thing is, you know you're not
3 alone. If you're here, you know that you're
4 not alone. We know that there's 38 million
5 people in the United States alone that have
6 hearing loss, some degree of hearing loss, and
7 that's one out of every ten. What we also know
8 about those people is that most of them are not
9 active in their health care and pushing forward
10 for new treatments. So the fact that you're
11 here, it's good. It means that you're a good
12 advocate for your own hearing health. So
13 that's very, very good.

14 And Cochlear is here to help. So you'll
15 see, we've spent 30 years that Cochlear's been
16 around, or more, trying to develop new
17 products, new things for people with hearing
18 loss. So the founder of our company,
19 Graeme Clark, was a brilliant scientist and his
20 father was deaf. So he made it his mission to
21 develop something for deaf people, and when
22 cochlear implants first came out people said,
23 "You're never going to be able to do that," but
24 we're proof that all these years later, the
25 technology is still improving, and it's a

1 wonderful technology. Many of you have a
2 cochlear implant.

3 So I'm going to talk about the different
4 types of hearing loss.

5 Right here, this is sensorineural hearing
6 loss. I hope that you can actually see this.
7 Sensorineural hearing loss is when your hearing
8 loss is affecting the inner ear or the cochlear
9 or the hearing nerve. Some people call it
10 nerve deafness, but that actually is not the
11 best connotation, I think, because sometimes
12 you can have a good nerve, a good hearing
13 nerve.

14 (Adjusting the microphone.)

15 ERIN: So what I was saying is that nerve
16 deafness would imply that there's a problem
17 with your nerve. Okay. The nerve is not
18 always actually impaired. Sometimes it's just
19 the little hair cells that are in your cochlea,
20 before you get to the hearing nerve.

21 So that's your cochlea. It's a little
22 tiny snail-shaped organ in your inner ear, and
23 that --

24 Did it just go out again? I'm just going
25 to go with this one.

1 (Adjusting the microphone.)

2 ERIN: Most of you or many of you have
3 some version of sensorineural hearing loss. It
4 may be a mild hearing loss, or moderate. We're
5 going to talk about the audiogram in a couple
6 of different slides.

7 So the next type of hearing loss is
8 conductive, and that means that actually not on
9 the inner ear, but it's actually in your middle
10 ear, similar to like when you have an ear
11 infection and things sound muffled, or if
12 someone is born without an ear, an external ear
13 or no ear canal, or if they have chronically
14 draining ears, that is usually a problem in the
15 middle ear space, but conductive loss can be
16 anywhere from the middle ear to the outer ear.
17 Something blocking. It basically just means
18 that something is blocking the transmission of
19 sound. Sometimes it's a physical thing. It
20 can be a tumor, which is like a cholesteatoma,
21 or it can be fluid or infection.

22 A mixed hearing loss is actually a
23 combination of the nerve or the cochlear
24 hearing loss and middle ear hearing loss. So
25 you could have fluid or infection or a tumor

1 and then on top of that you actually have
2 hearing loss in the nerve or the cochlea.

3 And then we have single-sided deafness,
4 which I heard someone say in the back they have
5 single-sided deafness. That means that you
6 have normal or very close to normal hearing on
7 one side, but the other ear is usually a
8 profound hearing loss. That's the technical
9 definition of single-sided deafness, but many
10 people actually use the term "single-sided
11 deafness" for someone who just has much, much
12 different hearing loss on one ear than the
13 other.

14 Any questions about that so far?

15 So we're going to talk about some of the
16 treatments for hearing loss. So you guys are
17 all probably very familiar with hearing aids.
18 Okay. So hearing aids have come a long way
19 even since I've started as an audiologist.

20 Hearing aids used to be huge. They used
21 to require very, very big batteries. They used
22 to be linear or analog. Nowadays they're
23 digital, and they're getting smaller and
24 smaller and smaller. We've got some hearing
25 aids now that I think I would lose, they're so

1 small. So that's great. We've seen just in
2 the short amount of time, probably in the last
3 ten to 12 years, we've seen hearing aids come
4 an enormous way, from being very, very big, not
5 very good sound quality, to small, but what we
6 do know is not everybody can get help from a
7 hearing aid, and that's why we have other
8 options out there.

9 One thing I'm going to talk about in depth
10 today is the cochlear hybrid, cochlear implant.
11 We also have just a regular cochlear implant,
12 which many of you have already. That is for
13 moderate to profound hearing, but more severe
14 hearing losses, and then a Baha. And that is
15 for mixed and conductive hearing loss.

16 So one thing that I have to say is that
17 you don't get to pick which one you get. Well,
18 sometimes. If it's just a hearing aid, you get
19 to pick, but if you want to go beyond that,
20 your doctor is the one that actually picks for
21 you based on your hearing loss. We don't get
22 to pick whether we get a Baha or cochlear
23 implant or a hybrid. It's your hearing loss
24 that determines that. The type of hearing loss
25 and the severity of the hearing loss.

1 So what we're also excited about is the
2 hybrid. So the hybrid cochlear implant has
3 been in development for a long time. There's a
4 doctor in Iowa that kind of dreamed it up 15
5 years ago and decided along with Cochlear we
6 were going to get together and make something
7 to help people who aren't benefiting from
8 hearing aids but are not quite to the point
9 where they're eligible for a cochlear implant.

10 Many of you have probably lived with
11 hearing loss for a number of years and
12 struggled with hearing aids. Many of you may
13 have worn hearing aids for 30 years, and your
14 hearing loss has changed over the years, and it
15 becomes more and more difficult sometimes to
16 communicate and to have relationships and to
17 hear what people are saying.

18 So the hybrid was really borne out of that
19 idea that we want to help people, somebody who
20 might have come into a doctor and said, "Is
21 there anything else out there for me because
22 these hearing aids are not helping for me, but
23 my audiologist says I'm not a candidate for a
24 cochlear implant." So the hybrid is kind of
25 for someone who is more in between.

1 So a lot of people with that kind of
2 hearing loss, which we actually as audiologists
3 call it a ski slope hearing loss, meaning it's
4 good or maybe even normal in the lower pitches,
5 but then it slopes off and we can't hear the
6 higher frequency sounds or higher pitched
7 sounds. So we're going to talk about what is
8 the hybrid, who can benefit from a hybrid, how
9 it works, and what's it's like to hear with a
10 hybrid.

11 MONTE: Are you also going to talk a
12 little bit about the Baha?

13 ERIN: Yes.

14 So when we talk about hybrid, many of you
15 might have heard of a hybrid car, and that is
16 combining two different technologies, the gas
17 engine and an electric engine together. It's a
18 hybrid engine. So the hybrid cochlear implant
19 is actually combining the best parts of a
20 hearing aid and the best parts of a cochlear
21 implant, to help those that can still benefit
22 maybe a little bit from a hearing aid but need
23 some extra help with certain pitch sounds.

24 So the hybrid is, just to be clear, for
25 someone who has a more significant high

1 frequency hearing loss.

2 This is really the first of its kind.
3 Cochlear has been studying this and researching
4 this for 14 years, and this hybrid cochlear
5 implant that's finally now on the market is the
6 first of its kind, and this is actually a
7 fourth iteration of the device that we've made,
8 but we think this one is the best one. So it's
9 the one we came to market with.

10 So some of you may know or identify with
11 being able to hear sounds or maybe being able
12 to hear that someone is talking but just not
13 having the clarity or being able to understand
14 all of the speech sounds, or being able to hear
15 music, but it doesn't sound as good as it did
16 years ago. Maybe missing hearing the birds
17 chirping. Certain sounds like that.

18 So actually in speech the sounds that are
19 high frequency are the consonant sounds, the
20 ones that make speech understandable for us.
21 So like a T sound, an S sound, a TH sound. So
22 when we don't hear those, oftentimes we
23 misunderstand the whole message.

24 For instance, if someone said the word
25 "cats" but if you didn't hear the "S" on the

1 end, you might think there was one. So those
2 possessives, but also consonants in general.
3 Consonants are what give us the clarity or the
4 understandability of speech.

5 So how it works, and I hope you can see
6 this, it's a little blurry, but sound comes in
7 through the microphone at the top of the ear up
8 here and transmits. So the hybrid is going to
9 transmit sound through your external ear,
10 low-pitched sound, but then it's also going to
11 digitally encode the high-pitched sounds and
12 send that across the coil to your cochlear
13 implant, which tells the inner ear which sounds
14 to hear.

15 So it's kind of like you're getting low
16 frequency sounds like from your hearing aid and
17 high frequency sounds from your cochlear
18 implant at the same time.

19 And then your hearing nerve is responding
20 to all of the sounds. So very many people who
21 have hearing loss for a long period of time,
22 they've only been hearing those low-pitched
23 sounds. So this is oftentimes able to bring
24 back or replace those high-pitched sounds.

25 Is everyone clear on the difference

1 between high pitch and low pitch? The
2 left-hand keys of the piano all the way up to
3 the right hand keys of the piano. I actually
4 had a patient tell me once -- they were a
5 musician -- and "I can hear, and when I get to
6 middle C, I still hear that, but as I keep
7 going up it stops. I can't hear anything
8 else." And they could actually track how their
9 hearing had progressed by which keys they could
10 hear on the piano. That's a savvy musician,
11 but we all know it could happen gradually,
12 happen overnight, but if it happens gradually,
13 you don't always know what you're missing out
14 on. We don't know what we don't know. We
15 don't know what we're not hearing. So
16 sometimes when people get activated with a
17 cochlear implant or hybrid, they're amazed by
18 what sounds they're able to hear again.

19 So a little bit about how the hybrid
20 works. I'll show you what everything is. Up
21 on the top -- and I can show you back on the
22 actual processor in the back, too, we have two
23 microphones here that are picking up sound.
24 Those two microphones work together. They're
25 synchronized and working together to figure out

1 where is the speech? What is the speech and
2 what's noise to try to help you hear best in
3 noise.

4 That is the actual speech processor.
5 That's the part that's like a miniaturized
6 computer. So interestingly, when cochlear
7 implants were first developed, when Dr. Clark
8 first developed the first cochlear implant, the
9 man who used it, he could only use it when he
10 was connected to the computer, and this was in
11 the '70s. So the computer was the size of this
12 wall, and he would have to come in and actually
13 physically plug in to be able to hear, and he
14 didn't want to go home at the end of the day
15 because he could hear, but he had to because
16 that big computer -- obviously he couldn't take
17 it home. So now it's much, much smaller. It
18 shows you how relatively quickly the technology
19 as moved where it is.

20 So this is the coil. I'm sorry, that's
21 the coil cable. And that is the coil, the
22 circle part up on the top, and that has a
23 magnet that attaches to the internal cochlear
24 implant. So there's two parts to it: The
25 outside part and the inside part.

1 Right here is actually the only part
2 that's implanted. So people think that the
3 whole thing is implanted. Actually, just the
4 little tiny piece is implanted into your inner
5 ear. The rest of the entire internal part just
6 sits on the top of your skull basically
7 underneath your skin.

8 And then here you see on the hybrid this
9 is the acoustic component or the hearing aid
10 part of the hybrid cochlear implant.

11 CHAR: So there's no processor with the
12 hybrid?

13 ERIN: Yes. It has the part that looks
14 like a hearing aid. So some of you I've seen
15 have some hearing aids that have the receiver
16 actually in the ear, and it basically just
17 looks like -- Maeve, do you want to pass it
18 around?

19 So there's a piece, a very thin wire that
20 you can barely see that puts sound right here,
21 and that's low-pitched sound, but the cochlear
22 implant speech processor just looks like a
23 typical cochlear implant speech processor.

24 CHAR: The picture that you show us -- I
25 thought that's all it looked like.

1 ERIN: This is the outside part and that's
2 the inside part.

3 CHAR: So this part here, is this part of
4 your cochlear implant, too?

5 ERIN: Well, so that's a nucleus six
6 speech processor, and anyone who uses one would
7 be able to use the acoustic component if they
8 have what we call audible hearing in the low
9 pitches. So if there's some hearing left in
10 the lows after surgery, you could potentially
11 use that acoustic component or the hearing aid
12 part.

13 AUDIENCE MEMBER: Can this work with an
14 existing cochlear implant?

15 ERIN: It can work with any nucleus
16 cochlear implant that -- where after surgery
17 the patient is still able to hear some
18 low-pitch sounds. So if you have anything but
19 a profound hearing loss after surgery, and you
20 have a nucleus device, you could use it.

21 So it's only been relatively recently that
22 we've thought there's a chance that we can
23 preserve low-pitch hearing. So we should
24 mention that. So when cochlear implants first
25 came out we thought any time you put anything

1 in the cochlea that you would lose all of the
2 hearing; whatever residual hearing you have you
3 would lose. And that is true for most cochlear
4 implants. The hybrid implant, this part, is
5 the only device that's ever been approved in
6 the US to preserve those low-pitched sounds.

7 AUDIENCE MEMBER: So are you saying that
8 the hybrid does not destroy the function of the
9 cochlea, that there is

10 ERIN: Yes, basically. So there's still a
11 chance, depending on your type of hearing loss,
12 there's still a chance that when you put
13 something in, that you could. There is always
14 a risk of losing hearing. So, on average, in
15 our study, study participants, most of them did
16 not lose hearing and most of them were able to
17 use the acoustic component, but there was a
18 percentage that were not able, that the surgeon
19 was not able to preserve hearing.

20 AUDIENCE MEMBER: That percentage is?

21 ERIN: About 30 percent of people did not
22 have hearing preservation, but of those -- and
23 I wasn't really going to talk about those, but
24 of those 30 percent, most of them do just as
25 well as someone with a typical cochlear

1 implant.

2 CHAR: Are you going to go into why it can
3 preserve? It doesn't go as far into the
4 cochlea?

5 ERIN: So yes. Our thinking is if you're
6 not putting it in as far, so if you're only
7 trying to stimulate those high-pitched sounds,
8 we only need -- Because the cochlea, if you
9 unraveled the whole part of the snail shell
10 part, one part is for high frequencies, one
11 part is for mid frequencies, one part is for
12 low frequencies. So the part that's farthest
13 out is the part that's only for high
14 frequencies. So if you put a tiny thin, thin,
15 electrode, and it's the smallest of its kind,
16 the thinnest electrode that's ever been made,
17 you put a little tiny one in there, and you use
18 a special kind of surgical procedure, and these
19 doctors are very highly trained -- a special
20 kind of surgical procedure and you minimize
21 trauma, then yes, the majority of people have
22 hearing preservation.

23 WALT: My wife was implanted about two
24 years ago, and unfortunately the implant
25 impinged on something in the cochlea and backed

1 out in the healing process. So she only ended
2 up with about two-thirds of the transmitter in
3 the cochlea. They tried to reprogram it. This
4 is CA, by the way. They tried to reprogram.
5 Finally said, "That's it" and installed a new
6 implant. I think it's seven. Whatever the
7 latest is. She was implanted in November.

8 I have one question. We've been working
9 now since November with the CA disk to improve
10 her hearing, and I know that the sound is
11 different coming in from the cochlear implant.
12 She's wearing a hearing aid in the other ear,
13 and the struggle has been enough that I'm
14 questioning whether her brain is having trouble
15 melding the different sound from the cochlea
16 and the straight sound from the hearing aid.

17 ERIN: That's definitely a valid
18 consideration. Some people who have worn
19 hearing aids for a long period of time -- well,
20 any patient who is eligible for a cochlear
21 implant who gets a cochlear implant has a risk
22 of not doing well with it. We hear about the
23 ones who do well most of the time, and the
24 majority of patients do very, very well with a
25 cochlear implant, but depending on the type of

1 hearing loss and how long you've had that
2 hearing loss, and what kinds of therapy options
3 are available to you, some patients can -- it
4 can take a much longer time to actually use
5 that hearing.

6 So when I was in the clinic talking to
7 patients, you know, I would say, "It's not a
8 guarantee that you're going to be hearing and
9 understanding on the first day." In fact, most
10 of the people in the room who have cochlear
11 implants can tell you they didn't understand
12 anything for the first couple of weeks to
13 months to maybe a year or so. So I've seen
14 patients that really do take a much longer time
15 to get to that point, and sometimes we have to
16 adjust their therapy, the kinds of therapy that
17 they're getting, and sometimes we have to
18 adjust our expectations, too.

19 So I would always tell patients that
20 there's a likelihood that you're not going to
21 hear with it, but we hope and from everything
22 that we see, we think that you're going to make
23 progress with it, but there is a chance, and
24 then it sounds like she's had some difficulties
25 with just the actual array staying in where

1 it's supposed to be. So that makes it much
2 more difficult, too.

3 AUDIENCE MEMBER: What percentage of
4 patients do these folks represent?

5 ERIN: It's a very small minority of
6 patients that don't --

7 AUDIENCE MEMBER: Less than one percent?
8 Less than ten percent?

9 ERIN: The actual device has a 98 percent
10 reliability. So meaning if it's in the
11 cochlea, it's putting out electrical
12 information. There's a lot of in-betweens
13 there. So we don't have -- Because everybody
14 does differently with a cochlear implant, and
15 because everyone's expectations are different.
16 So someone who is born with hearing loss and
17 had hearing loss for 50 years is going to have
18 a very different outcome. It's really hard to
19 track those kinds of things. The majority of
20 people hear with their cochlear implant.
21 That's what I can say.

22 CHAR: It's so funny because new people
23 who are considering the cochlear implant,
24 getting a percentage number gets to be very
25 important to them. Okay. But I want you to

1 remember that if you go and have a root canal
2 from a dentist, it's not always going to work.
3 It works for most people, but not everybody.
4 If you have knee surgery, it works for most
5 people, but there's a few people that it's not
6 going to work for. So cochlear implants are
7 exactly the same thing. There's no guarantees
8 in life. Period.

9 ERIN: And just to be clear, Cochlear as a
10 company has the most reliable on the market.
11 We've been around the longest. We have the
12 most recipients, and of those recipients,
13 98 percent have a functioning implant.

14 DOLLI: When you have a cochlear implant
15 surgery, people react to that surgery
16 differently. Some people can hear immediately,
17 like I did. Immediately. Others, it takes
18 time for you or the audiologist; it takes time
19 for it to work. It depends on the type of
20 hearing loss you have and other things.
21 Everybody I know in here that wears cochlear
22 implants has been helped.

23 ERIN: So this is just a generality, but
24 someone who has had hearing and lost it and has
25 only had that significant hearing loss for a

1 short period of time tends to do very well very
2 quickly. Someone who has had hearing loss for
3 a long, long time tends to need more time to
4 adjust. So that's just in general.

5 WALT: I didn't want to discourage anyone
6 that's considering a cochlear implant by what I
7 said. The surgeon at Kaiser said that this is
8 most unusual. There was some growth or
9 something inside the cochlea that the probe
10 impinged on, and he said although it seemed to
11 all go in fine, in the healing process it
12 backed out. When he installed the new probe,
13 which is slightly smaller, before he put the
14 new one in he tried to reinstall the old one,
15 and whatever was blocking it, all of a sudden
16 he said -- It went in, but he had nicked the
17 cable a little bit playing with it. So he
18 tossed it over his shoulder and put a new one
19 in.

20 And we've had probably in the last ten
21 days a little breakthrough, and we're working
22 with the cochlear disk and with random words
23 out of the newspaper and we're getting a little
24 better now, kind of all of a sudden.

25 ERIN: Good, good. It does take time, and

1 you need to be patient with yourself and your
2 spouse or your friends who have cochlear
3 implants because it can definitely be a
4 struggle. Sometimes it makes them just
5 physically exhausted. It's really hard. It's
6 really hard listening with hearing aids, right?
7 It's even harder in the beginning to listen
8 with a cochlear implant. People really need to
9 focus, and all of the acoustics of the room
10 need to be really great. Everything needs to
11 be perfect. Maybe minimal noise. It sounds
12 like you're doing great and doing some therapy.
13 So good for you for doing all that.

14 AUDIENCE MEMBER: If I understood the
15 hybrid, there is some hearing functionality
16 preserved in the cochlea, whereas the regular
17 cochlear implant it's destroyed? There's total
18 loss, correct?

19 ERIN: In the FDA indications, it says
20 that if you get a regular cochlear implant, you
21 will lose all of your hearing. We know there
22 are cases where that's not always true. In
23 fact, we have another cochlear implant device
24 that's designed for people who have worse
25 hearing than a hybrid candidate would have that

1 actually is able to preserve some hearing, but
2 it's not approved for that reason. It's just
3 that if everything's right, you can preserve
4 hearing with a regular cochlear implant. It's
5 just much more difficult.

6 AUDIENCE MEMBER: If someone is approved
7 or whatever the word for the implant, does that
8 mean they're automatically approved for --
9 eligible for the hybrid?

10 ERIN: No. That's a great question
11 actually. So the FDA has approved both, but
12 they're separate indications. So a cochlear
13 implant candidate is assessed or evaluated
14 using sentences. So your audiologist would
15 test you in a booth with recorded sentences and
16 see how many words out of all of the sentences
17 that you're able to understand. For Medicare
18 you have to get less than 40 percent on that.
19 For commercial insurance it's less than
20 50 percent of the sentences, but what we know
21 is that sentences are a lot easier than single
22 words.

23 For hybrids, because we know they have a
24 lot more hearing coming to the table, we have
25 to make it a little more difficult for them.

1 So we use words, single words, like "carve,"
2 things like that. So they're looking at how
3 many of the words you're getting correct or
4 even sometimes how many of the individual
5 speech sounds that you're getting correct. So
6 that's different. So whether they test you
7 using sentences or words, for a hybrid it's up
8 to 60 percent. So less than 60 percent on the
9 word test.

10 AUDIENCE MEMBER: Less than 60 percent
11 you're eligible?

12 ERIN: Yes, by FDA guidelines.

13 CHAR: This is so funny. Well, it's not
14 funny, but to give you an example, I would not
15 want to preserve any hearing in the ear that I
16 got implanted in because the hearing that was
17 in that ear was so distorted. You know, it
18 wasn't a matter -- I could hear it, but it was
19 distorted. Why would I want to keep that
20 distortion, along with the great sound that's
21 coming through my cochlear implant? And then
22 you may not have enough hearing. So if you
23 have just a very small percentage of hearing,
24 you're not going to -- it's not going to do you
25 any good anyway if you keep that hearing.

1 ERIN: So you would not be eligible for a
2 hybrid if you had very little hearing left.
3 Because then we're not -- we want a full length
4 array. We want you to be able to get the full
5 array and get complete cochlear coverage. That
6 means the array goes in further.

7 To your point, you didn't have good speech
8 understanding before. Many of these hybrid
9 candidates that have good low frequency
10 hearing, they can actually do fairly well in a
11 quiet situation or one on one. It's when you
12 put any sort of noise in the background or you
13 get in a group situation or basically any other
14 situation than a quiet room with one other
15 person.

16 So that's why we had to make the test
17 harder to be able to evaluate who would benefit
18 more from a hybrid than a cochlear implant. So
19 it's easy to say, "Oh, you're not hearing
20 anything."

21 AUDIENCE MEMBER: In a group situation is
22 there a substantial difference in performance,
23 understanding, comprehension rather between the
24 hybrid and the regular implant?

25 ERIN: If you're able to use a hybrid to

1 its fullest extent and use the acoustic part
2 and the electric part, yes, much better. So
3 the average is 76 percent. So that's very,
4 very good because the average cochlear implant
5 user gets about 55 percent. So if you're able
6 to use the whole system, like it was designed,
7 you could do much, much better. In fact, the
8 trial recipients -- Thank you for the segue.
9 So the trial recipients did at least two times
10 better than they did with their hearing aids,
11 if they were able to use the hybrid.

12 We looked at just our cochlear implant
13 clinical trial from years ago and looked at the
14 results of 50 subjects, of those 50 subjects,
15 and compared them to our hybrid subjects. They
16 look very similar. Even if you aren't able to
17 preserve all the hearing in that ear, you're
18 going to do as well as someone with a typical
19 cochlear implant, but if you can preserve the
20 hearing and use the acoustic part, then you're
21 going to do much better than someone with a
22 cochlear implant.

23 AUDIENCE MEMBER: What's the chance of
24 your low frequency hearing degrading?

25 ERIN: That's a really good question. We

1 don't know. That's very person dependent. So
2 depending on your type of hearing loss, you may
3 not be a candidate for a hybrid if your doctor
4 feels like there's a likelihood that you could
5 lose hearing over time. So we want to implant
6 subjects that actually we think their hearing
7 has a good chance of stabilizing and not
8 progressing. So that's actually a
9 contraindication. If you've had a progressive
10 hearing loss that hasn't stabilized, you would
11 not be a candidate for a hybrid most likely.
12 But you could be a candidate for a typical
13 cochlear implant, and even if you got a typical
14 cochlear implant, if they were able to preserve
15 some hearing, you can still use what we call
16 hybrid hearing. You just don't have the hybrid
17 implant. I hope that's clear. That's a lot of
18 stuff to understand there.

19 Yes?

20 AUDIENCE MEMBER: If you have almost lost
21 all of your hearing, is it best to get this
22 done before you lose the whole -- Is that what
23 you're saying?

24 ERIN: Yes. So if you are losing hearing
25 progressively, it would be best to probably not

1 get a hybrid. It would be best to get a
2 typical cochlear implant. So if you have
3 stable hearing in the low pitches and we're
4 trying to preserve that, then that's a good
5 candidate for a hybrid. If your hearing is
6 quickly progressing and you've almost lost it
7 all, it's best to not get a hybrid and get a
8 regular cochlear implant. And then any person
9 who gets a cochlear implant does a little bit
10 better if they get it before they have lost it
11 all.

12 AUDIENCE MEMBER: What about if your
13 hearing goes in and out? Sometimes you hear
14 and it clicks on and off?

15 ERIN: Fluctuating hearing loss is
16 usually -- You have good days and bad days,
17 right? But then it slowly tends to be more bad
18 days, but then you have an occasional good day.
19 Still, probably you would want to go with a
20 typical cochlear implant, depending on how much
21 hearing you have left, because we just don't
22 know. Whatever is causing your hearing to
23 go -- you know, it could be better on some
24 days -- could also make it more likely that you
25 would lose hearing during the surgery.

1 But I actually had a patient that had an
2 ear that we called dead, as an audiologist. It
3 had not had any stimulation since he was three,
4 and then a ear that fluctuated for very many
5 years, and got an implant in both ears, and he
6 said the hearing that he got from his implant
7 on the fluctuating side was so much better
8 because it was stable. It didn't go up and
9 down. The hearing that he got from the other
10 side that hadn't had a hearing aid for -- and
11 hadn't hearing was much, much different. So
12 just in that same person, the difference is
13 amazing, and those of you who have two implants
14 may have one ear that's better than the other.
15 That's very common.

16 So I don't want to leave this out. The
17 participants in our hybrid cochlear implant
18 trial that we did with the FDA, we've been
19 working on for several years, the FDA wanted us
20 to do a questionnaire with them to make sure
21 that their satisfaction was good, and they had
22 ten times the level of satisfaction with their
23 hybrid than they did with their hearing aids.
24 So that's pretty good. They were not satisfied
25 with their hearing aids except in quiet before

1 they got their hybrid.

2 AUDIENCE MEMBER: Can you adjust the
3 focus? (Referring to the slide show)

4 ERIN: I don't know.

5 MAEVE: I'll try.

6 ERIN: That's better. I just thought it
7 was because it was the sheet, but it's much
8 better. I'm sorry.

9 MAEVE: Can you start over?

10 ERIN: Anybody who wants to come back and
11 look at the slides later on that were fuzzy,
12 let me know.

13 AUDIENCE MEMBER: Are copies of this
14 presentation going to be available?

15 ERIN: If you give me your e-mail, I can
16 send you any of the slides that you'd like.

17 So just about the nucleus six processor.
18 We've got this in the back. I think it's the
19 most technologically advanced processor that's
20 available on the market right now. It has an
21 amazing processing chip. The chip that's
22 inside this processor is five times more
23 powerful than the previous generation. So not
24 only does it do a lot right now, it's capable
25 of doing quite a bit in the future, and even in

1 the near future we're going to have some
2 technologies that are available later this year
3 that are going to help you hear even better.

4 So one of the biggest is its wireless
5 capabilities. So you can see in the back we
6 have some wireless accessories available for
7 the Baha, and Maeve might briefly touch on
8 these, too. These are going to be available in
9 our nucleus, in our cochlear implant processor
10 as well by the end of the year, and essentially
11 what it is is just things to help you hear
12 better. There's a completely wireless phone
13 clip where you don't have to wear anything
14 around your neck at all. So completely
15 wireless. Your phone would ring into your
16 Baha, or into your Baha or your implant, and
17 you wouldn't have to wear anything around your
18 neck.

19 Another thing is the mini microphone. So
20 you could give it to your spouse or a friend or
21 put it on the table in a restaurant, and it's
22 going to be amplifying only the voices that you
23 want to hear, not the noise in the background.
24 It's amazing.

25 AUDIENCE MEMBER: So Bluetooth capability

1 is available with the Baha, not the regular
2 cochlear implant?

3 ERIN: So when the processor was approved,
4 the FDA wanted more information on some of the
5 other capabilities, and so we've just been
6 giving them that and doing studies, and we're
7 estimating it's going to be available in the
8 next few months.

9 AUDIENCE MEMBER: And the hybrid?

10 ERIN: The hybrid as well. Anything that
11 is available for the cochlear implant is
12 available for the hybrid as well because it's
13 the same processor.

14 AUDIENCE MEMBER: The hybrid is available
15 now?

16 ERIN: Right. The hybrid is available
17 now. Sorry, I should be clear. The hybrid was
18 approved, and just so you know, the FDA had a
19 panel back in November of doctors and
20 audiologists, and all of those doctors -- it
21 was overwhelming, unanimous response saying
22 yes, they thought this should be approved, and
23 then it just took a couple months to get the
24 formal approval through. So it's been approved
25 for a couple of months now.

1 WALT: This device you mentioned to put on
2 the table to just pick up the voices at the
3 table and block out all background noise, is
4 that available now for full cochlear implant?

5 ERIN: No, that's only available in the
6 Baha, but it will be available by hopefully
7 this fall. So pretty quickly.

8 GRACIELA: I was going to ask, and Char
9 brought this point, and you might have covered
10 it. If you have some hearing, but there's
11 some, you know, where you don't understand or
12 some distortion, that's not going to improve?
13 It's going to stay the same?

14 ERIN: That's a great question. So
15 usually the part --

16 CHAR: Can you repeat the question?

17 ERIN: She asked, "Is it going to
18 improve?" So if you have understanding but
19 it's not good understanding before you get a
20 hybrid, is it going to approve? So most
21 people, their hearing loss is worse in the
22 higher frequencies, the higher-pitched sounds.
23 So it might be good -- you might be able to
24 hear voices, but you just can't understand what
25 they're saying, what the speech is. So because

1 speech is mostly high-frequency sounds or
2 high-pitch sounds, if you take away the high
3 frequencies, you don't have the understanding
4 there.

5 So what the hybrid does is lets you keep
6 the low pitches that you have with your hearing
7 aid and replaces the high frequencies. So most
8 of the time people get back the understanding
9 because they're getting the high frequencies
10 again they weren't able to get with their
11 hearing aids. Hearing aids have limitations.
12 Even the best, most expensive hearing aid in
13 the world is not going to be able to amplify or
14 make louder some of those high-frequency
15 sounds, and even when they can, it doesn't
16 necessarily bring back the understanding. Does
17 that make sense?

18 So your good hearing that you have is in
19 the low pitches. That's what a hybrid could
20 preserve. It's not going to preserve those
21 high frequencies because we're not worried
22 about those. We know you're going to hear
23 better with an implant for the high
24 frequencies, but the low frequencies give you
25 better music understanding, better speech

1 understanding in noise, and just better sound
2 quality.

3 AUDIENCE MEMBER: I know this is the holy
4 grail, but does it do any better than hearing
5 aids in helping you in a crowded environment?

6 ERIN: Yes. Implants in general are
7 vastly better than hearing aids in noise. So
8 every study that's ever been published shows a
9 cochlear implant is much, much better in noise.
10 A hybrid, if you're using it to its fullest
11 extent, is going to be even better than that.
12 So the hybrid trial participants did very, very
13 well in noise, and their understanding of music
14 was almost like a normal hearing person as
15 well. It's really remarkable, very exciting
16 for me to finally get to see it come out.

17 AUDIENCE MEMBER: I know you mentioned
18 high frequencies and low frequencies. How do
19 you quantify and define what is considered a
20 high frequency and what is considered a low
21 frequency?

22 ERIN: That's a good question. Actually I
23 don't have a picture of the audiogram on here,
24 but on your audiogram, things that are on the
25 left-hand side of your audiogram -- we quantify

1 pitch in hertz. That's H-E-R-T-Z. That's how
2 we measure pitch. Lower frequencies, like 125,
3 250, 500, a thousand, up to 2,000, the hybrid
4 acoustic component can amplify those. Anything
5 above that, so 3,000, 4,000, 5,000 -- So speech
6 is anywhere from about 250 to 8,000 hertz. So
7 the low frequencies of the speech are going to
8 be amplified by the hearing aid part or
9 acoustic part, and the high frequencies are
10 going to be amplified by the cochlear implant
11 part. Did that answer your question?

12 So the scientific term is hertz, and
13 that's how we quantify it. Anything below
14 2,000 hertz, which is speech -- most speech
15 sounds, like a vowel, vowel sounds are mostly
16 low frequencies. Consonant sounds are high
17 frequencies. Low-frequency environmental
18 sounds would be like --

19 GRACIELA: On the music, I hear the music,
20 but it's the lyrics that most of the time I
21 don't know.

22 ERIN: She's saying she can hear music but
23 can't understand the lyrics. So the lyrics are
24 speech and they're mostly high frequency. So
25 if you take away the high frequency, you're not

1 going to be understanding the lyrics or the
2 speech sounds within the music. A lot of music
3 is lower frequency. So you can detect it, but
4 understanding it and processing it and being
5 able to discriminate between the different
6 sounds, you need high frequencies for.

7 So I want to briefly talk about steps to
8 getting a hybrid. It's very similar to getting
9 a cochlear implant. Many of you have already
10 gone this route. So step one is a hearing
11 evaluation. Usually that's done by an
12 audiologist, but it could be a hearing aid
13 dispenser who does the hearing evaluation and
14 recognizes that you're not getting as much
15 benefit from a hearing aid as you may be used
16 to or as you could.

17 Then a medical evaluation by a doctor who
18 does cochlear implants to be able to determine:
19 Can we even get a cochlear implant in there?
20 Is your type of hearing loss one that is
21 suitable for a cochlear implant?

22 Then the actual hearing implant procedure,
23 which is not brain surgery. A lot of people
24 think that, "Oh, they're drilling into my
25 head." It's nowhere close to the brain. So

1 the closest it gets to the brain is it's close
2 to or affecting one of the nerves, which is
3 your hearing nerve. So it's very close to that
4 nerve, but it's nowhere close to the actual
5 brain.

6 So your cochlea is actually in the hardest
7 bone in your body, your temporal bone right
8 here. The complications are usually very, very
9 minimal, and most people go home the same day.
10 It's usually about a two-hour procedure, and
11 most people have very minimal pain. Sometimes
12 there's a little bit of dizziness or offbalance
13 feeling for the first day or two, but most
14 people don't have that issue, and the only pain
15 is really associated with the incision, just
16 feeling like that incision -- similar to when
17 you get stitches.

18 AUDIENCE MEMBER: Tinnitus?

19 ERIN: So some people actually have
20 TINnitus or tinNItus. You can pronounce it
21 either way. Some people have that before
22 getting a cochlear implant, and sometimes they
23 feel like wearing their cochlear implant makes
24 it better. Some people get it after the
25 surgery for a few days, and then once they have

1 the activation or turn on their implant, they
2 don't hear it as much any more. Usually it
3 helps.

4 And then the activation of the cochlear
5 implant is usually done within two to four
6 weeks, depending on what your doctor says.
7 That's where you come in and sit down. They
8 hook up your cochlear implant speech processor
9 to a cable that's connected to the computer,
10 and the audiologist is actually mapping or
11 programming how much electrical stimulation
12 you're going to get from the cochlear implant.
13 And it usually takes a couple of hours, one to
14 two hours.

15 CHAR: Just a few more minutes and we'll
16 take a break.

17 ERIN: She says it sounds like a miracle.
18 Ask anyone who has one what they were missing
19 out before. Most people who have cochlear
20 implants wish they would have done it sooner.

21 And then the final and probably most
22 important step of the journey is making sure
23 that you're doing therapy exercises and working
24 on trying to make your hearing, best and your
25 audiologist will give you individual exercises

1 for you depending on where you are at that
2 point.

3 We can just skip through because I want
4 Maeve to be able to talk. We had a lot of
5 questions, and they were great questions, but I
6 don't want to go over the time. If you guys
7 have a specific question, just come ask me
8 later.

9 Do you want to take a little break?

10 CHAR: I think we should take a break.

11 Let's take a shorter break because afterwards
12 we're going to talk about the Baha, and that is
13 really fascinating. People who have some metal
14 put in their teeth, all of a sudden they start
15 hearing better? And I noticed similar things.
16 Like I'm thinking, "Well, I could use the Baha
17 and the cochlear implant," but I'm kidding.

18 So let's just take a ten-minute break and
19 come back. Please stick around for the Baha
20 presentation. Okay? Cookies, coffee.

21 (Break.)

22 CHAR: I'm sorry to end the break, but we
23 have so much information. If you want to
24 stretch and get the oxygen flowing to your
25 brain.

1 CHAR: This is about the Baha. I think
2 how wonderful it is today. Like Eric is
3 saying, we have all this wonderful technology.
4 It is the most wonderful thing. And we're very
5 lucky, those of us who can take advantage of it
6 and use it, because it wasn't so long ago if
7 you went deaf, you just went deaf. There
8 wasn't much you could do about it. So this is
9 really exciting.

10 Let's go on and talk about the Baha. This
11 is Maeve.

12 MAEVE: Can you hear me?

13 All right. Well, don't be as tough on me.
14 You're an educated audience.

15 So good morning. My name is Maeve Browne,
16 and I'm the engagement manager for Cochlear.
17 I've been with the company going on 15 years
18 now. So anything I can do to help you on your
19 journey or answer any questions, I would be
20 happy to.

21 Up till recently, until I took the
22 engagement manager position, I was doing
23 surgical support. So when people come to our
24 local chapter meeting, many of them I was in
25 the operating room when they had their surgery.

1 So we kind of continue on that journey
2 together. So when we say hear, now and always,
3 we mean it.

4 So the Baha, you'll notice that it's a
5 capital B and a small -a-h-a, and typically
6 when you read literature you'll see it all
7 capitals. So Baha stood for Bone Anchored
8 Hearing Aid, but back in 1996 when Medicare
9 started to approve the Baha as a system for
10 hearing loss, they would not approve it with
11 the word "hearing aid" in it. So we changed it
12 from BAHA all caps and for it meaning anything,
13 and that's just our product name, Baha. Any
14 other company that does bone-anchored solutions
15 use the all-caps just to describe the product,
16 but it's not the product name. So just a quick
17 disclaimer there.

18 So interesting to note that the Baha was
19 actually invented in Sweden right around the
20 same time as Graeme Clark was working on the
21 cochlear implant, back in 1977. Dr. Per
22 Branemark, -- and if anybody has had a dental
23 implant, they may have heard of the Branemark,
24 the Branemark dental implant. Dr. Branemark
25 was working on the properties of titanium in

1 bone and how to get titanium to stay in bone.
2 So titanium is a scavenger metal, and it is
3 almost never rejected by the body. So it's the
4 one like titanium pins, you get -- The casing
5 on your cochlear implant is titanium. It's not
6 rejected by the human bone.

7 So he was working on that, and the patient
8 he had in the chair had single-sided deafness,
9 and when he put the implant in and he was
10 pounding on -- putting the abutment on, the
11 patient said, "I can hear when you do that,"
12 and that was kind of the aha moment.

13 So he brought in his friend who was an
14 otolaryngologist, I guess. His name is Dr.
15 Chelstrom, Anders Chelstrom. He brought him
16 in, and they put a bone conduction device on
17 the implant while the patient was in the chair
18 and the patient could hear. So that was how
19 the Baha came about.

20 So the same implant is still being used
21 today for Baha. Cochlear about three years ago
22 changed the design on it, and we're working
23 closer and closer with the dental industry in
24 using different coatings and different -- I
25 would say coatings, roughness on the implant to

1 make it more -- to make it easier to integrate
2 with the bone, and the process of that is
3 called osseointegration, and that means bone
4 growing over metal.

5 So that takes -- that process takes about
6 six weeks for it to be completely
7 osseointegrated into the bone.

8 So today of course Erin and I were talking
9 about that earlier. We start talking and
10 forget we have slides. The Baha Attract is our
11 newest Baha system, and it is a magnetic
12 system. The surgical procedure is still
13 relatively the same, but this is really nice
14 for people who don't want to deal with an
15 abutment. Once it comes off, it's gone. You
16 can't see it. Put it back on, you can hear.

17 So we took what we know about cochlear
18 implant magnets and took that into the Baha
19 technology. So we've been working on this for
20 a long time. The system, what is unique to the
21 Baha Attract system is that it still uses an
22 osseointegrated implant. So the surgeon still
23 puts a three millimeter or four millimeter
24 implant into the bone, right here on the
25 mastoid bone right behind the ear, right at the

1 level of the ear canal or the top of the pinna.

2 And with the attract the process can be fit

3 after four weeks, four weeks after surgery.

4 So who is a candidate for this? Somebody

5 who has single-sided deafness. So, like Erin

6 explained, who is deaf in one ear but has

7 pretty good normal hearing on the contralateral

8 ear, on the opposite side. Somebody who has

9 atresia, which is complete blockage of the ear

10 canal, so the ear canal never formed and so

11 there's no way for the sound to get into the

12 ear canal.

13 We see a lot of children these days, I'm

14 not quite sure why, but a lot of little boys

15 are born with microtia and atresia, which means

16 the ear lobe never developed. We don't know

17 what it's due to. I always say it's pesticides

18 or something because a lot of it is north of

19 LA, the Bakersfield area; we see a huge amount

20 and we also see a lot of children coming from

21 Mexico with atresia and microtia, and

22 particularly boys and on the right ear. It's

23 strange.

24 So those are perfect candidates for an

25 Attract because they just need to drive the

1 sound to that particular ear. So for atresia
2 and microtia, they drive the sound; they
3 implant the side that doesn't have the pinna,
4 and then they may have a reconstructive ear
5 over time. And that's a whole 'nother story.

6 And somebody with single-sided deafness,
7 we would implant the Baha on the deaf ear, on
8 the deaf side. So while it doesn't cure
9 hearing loss, like the cochlear implant isn't a
10 cure for hearing loss either, but it definitely
11 works on the hearing nerve. With the Baha it's
12 not doing anything on that side. That will
13 always remain a dead ear.

14 What the Baha does is it takes the sound
15 on the deaf side and vibrates the bone, which
16 is why you have the little metal implant in
17 there. It vibrates the sound and goes through
18 the bone to the good normal hearing ear. So
19 you have the impression of hearing from both
20 ears, and it will help the localization, but it
21 doesn't actually fix the hearing on that side,
22 but it's one of those -- you can try it.

23 So our friend Rosemary is going to demo it
24 after. If anybody else thinks they may be a
25 candidate for a Baha, we can demo it on you

1 after. That is a nice thing that a lot of
2 audiologists will let you borrow a Baha
3 processor and wear it for a week or so and go
4 about your normal daily life and see if it
5 provides an improvement.

6 So that is the Attract.

7 And then the Connect still has the
8 abutment. So this was the original Baha, and
9 so when you snap off the processor, there's an
10 abutment on there, and a lot of people still --

11 I'm low on batteries. Excuse me for one
12 second.

13 (Adjusting the microphone.)

14 MAEVE: Yes, so the Connect uses the
15 abutment. It also provides a little more
16 power. So if you do have a mild sensorineural
17 hearing loss on the opposite ear, then you
18 probably would be a candidate for the Connect
19 with the abutment because it does provide -- it
20 goes up to a 65 dB loss. This ideally goes to
21 a 45dB. So if you're not going to have any
22 progressive hearing loss on the other ear, then
23 by all means you can get the Attract.

24 The nice thing about our system is,
25 though, because you still have the implant in

1 there, if you did need to go -- over time if
2 you did have a progressive hearing loss, the
3 surgeon can remove the magnet and place an
4 abutment. So you do have somewhere to go
5 after, if that doesn't work.

6 And I'll pass this around, but this is
7 what the internal magnet looks like, and the
8 processor then connects to that. If anybody is
9 interested. That's about the size of it.

10 And it's all under the skin. You can't
11 see it. It's a -- the incision is probably
12 like a cochlear implant incision, maybe a
13 little bit smaller, but healing time is very
14 fast.

15 CHAR: How long does surgery take? Do you
16 call it surgery?

17 MAEVE: It's outpatient. With an
18 experienced surgeon, and we have many here in
19 San Diego, it's about 20 minutes. It's very
20 fast.

21 AUDIENCE MEMBER: When I was told about
22 the Baha, I was told that there's kind of a set
23 kind of a hygiene care that you have to keep it
24 clean and do all that kind of -- and that kind
25 of bothered me and I wondered how much of a big

1 deal that would be.

2 MAEVE: It becomes habit over time, but it
3 is really important, and through my years of
4 working with the Baha, if I'm training a new
5 ENT on all the surgical procedures and talking
6 about who would be a good procedure, if you
7 have somebody who comes into the office and
8 they don't clean their teeth, they're probably
9 not going to take care of their abutment. So
10 if they have "summer teeth" -- some are here,
11 some are there -- they're not going to be a
12 good Baha candidate.

13 We provide a little brush that you clean
14 the abutment. When you're in the shower,
15 washing your hair, just take the brush and wipe
16 the abutment. That's pretty much it. It's not
17 a big laborious --

18 ERIN: But if you have an Attract --

19 MAEVE: If you have an Attract, then
20 there's no maintenance. Once your incision
21 heals, then you're good to go.

22 AUDIENCE MEMBER: I had another question
23 about progressive hearing loss. I continue to
24 have my hearing checked ever year, but that was
25 one thing that was brought up to me, too; if I

1 do have a progressive hearing loss in my good
2 ear, that that would have to be addressed, too,
3 at that time. So how do you know if you're
4 going to have progressive hearing loss?

5 MAEVE: You don't. You look at over time
6 that you have over the years, how
7 progressive -- how fast has your hearing loss
8 declined?

9 AUDIENCE MEMBER: Two years ago it hadn't
10 declined. So I have it every two years. So I
11 guess this year I'm supposed to have another
12 one and I'll see if it's progressed or not.

13 ERIN: Most audiologists would consider it
14 to be stable if it hasn't changed in five
15 years, or if there's been less than a ten
16 decibel change in five years.

17 CHAR: So I'm trying to get it. So you
18 have the deaf ear, and this Baha collects the
19 sound?

20 MAEVE: So the sound comes in through this
21 sound processor.

22 CHAR: Just like it would be through a
23 hearing aid processor?

24 MAEVE: Exactly. It comes in. It
25 evaluates the sound, cleans it up, and then it

1 sends it through. There's what we call a
2 transducer right here on the back of the
3 processor, and that vibrates inside the
4 abutment. It vibrates, and so it vibrates the
5 bone. So if somebody with normal hearing gives
6 themselves a conductive loss, like you plug your
7 ears, and you put the Baha on the forehead, you
8 can hear what the Baha sounds like. It
9 vibrates.

10 You can hear -- Sound travels faster
11 through solid mass than it does through air,
12 right? So if you, for example, listen to -- I
13 hear myself talk and I always hate the sound of
14 my voice, and then I hear myself on a voice
15 message that I've left for somebody and I say,
16 "I don't sound like that." It's because that's
17 the difference between bone conduction, "I hear
18 my own voice," and air conduction when you hear
19 it through another method.

20 CHAR: How does the sound get over to the
21 other ear?

22 MAEVE: It goes right through the skull.

23 ERIN: Do you have a slide that shows?

24 MAEVE: I don't, but I can show you in the
25 brochure. I can show you how that works.

1 CHAR: It goes through the -- Does it go
2 on top --

3 MAEVE: It goes right through the bone.
4 It's going through the bone so it's vibrating
5 through the bone. It's instantaneous. There's
6 no time lag. And you don't feel the vibration.

7 AUDIENCE MEMBER: Is it like a crossover
8 hearing aid?

9 MAEVE: Exactly, but it's direct
10 conduction.

11 WALT: I'm really confused. If both sets
12 of sound are going to the same ear, how do you
13 get location out of it?

14 MAEVE: You get a sense of knowing where
15 the sound is. You know it's different. So you
16 still hear it coming in on this side. So if I
17 am deaf in one ear and I go to a restaurant and
18 I'll tell you, "Don't sit on my deaf side, I
19 can't hear you," when I have a Baha on, I can
20 hear you on that side. So the sound is still
21 coming in on that side. The brain is an
22 amazing organ and it can make that distinction
23 on which side the sound is coming in on, but
24 actually it's your hearing nerve on the good
25 ear that hears. It's one of those, "Oh. It

1 works like that? How did they do that?"

2 AUDIENCE MEMBER: Since I had my surgery,
3 I have a constant -- It's like a radio signal
4 in my bad ear. It's constant. It's 24 hours a
5 day. And so I think that has something to do
6 with when you put the Baha in how the sound is
7 transferred because my bad ear is picking up
8 signals, but the mechanisms to hear it aren't
9 working. So that's why I have that signal all
10 the time in my ears.

11 ERIN: You're hearing tinnitus, and that's
12 pretty much one of the most common symptoms of
13 hearing loss, is that you have ringing, or
14 sometimes it's not ringing. Sometimes it's a
15 different type of noise. Sometimes it can
16 sound like crickets or just a steady noise.
17 Sometimes it sounds like waves. Sometimes
18 people say it sounds like voices. Tinnitus,
19 it's your brain reacting to not having
20 understanding of speech over there any more.

21 AUDIENCE MEMBER: They didn't tell me
22 about that before my surgery.

23 MAEVE: What surgery did you have?

24 AUDIENCE MEMBER: I had acoustic neuroma.

25 MAEVE: That is one of the major

1 indications for a Baha, is an acoustic neuroma.

2 CHAR: This is similar to the crossover
3 hearing aids?

4 MAEVE: Yes. So the cross is the
5 nonsurgical. It's a nonsurgical option.

6 CHAR: Will insurance pay for the Baha?

7 MAEVE: Yes, insurance pays for the Baha.

8 CHAR: So that would be a reason to get
9 the Baha versus the crossover?

10 MAEVE: Thank you. Yes. I'm glad you
11 mentioned that, Char. It is covered by
12 insurance, yes. Once Medicare approved it, and
13 it's considered a prosthetic. So it's an
14 implantable solution. So we work with the
15 hospital to make sure that they order the sound
16 processor at the same time as the implant so
17 that you don't have to pay for that out of
18 pocket.

19 CHAR: What determines the sound quality
20 from coming over here? The processor takes the
21 sound in?

22 MAEVE: It's programmed. It can be
23 programmed for each individual person. You sit
24 down with the audiologist, and they look at
25 your audiogram and they plot where the sound is

1 coming in, and almost like with a cochlear
2 implant mapping session, you know, "Is this
3 comfortable? Can you hear this?" And so they
4 program it to the individual's hearing loss.

5 CHAR: It's amazing.

6 MAEVE: And there are different programs.

7 I'll talk about this because we have a new
8 processor called a Baha Four that we just
9 released in November, and it's got a lot of the
10 same technology that the cochlear implant has,
11 and it was the first with the wireless with the
12 2.4 gigahertz platform. So we partnered with
13 Resound. So if anybody is familiar with
14 Resound and their technology, and they really
15 are coming to the fore with a lot of their
16 wireless capabilities. They have the new
17 links, which uses an iPhone with no
18 intermediary, no -- What's the word?
19 Transmission.

20 And so we're really happy that we
21 partnered with them because we are now using
22 their technology. With the mini mike,
23 everybody just loves the mini mike. That's
24 been the -- Probably 80 percent of people are
25 getting the mini mike. It's a wireless

1 microphone, and so say, for example, a child is
2 at school, and they typically wear an FM
3 system. Now they no longer need the FM system
4 in the classroom. They walk in, they give the
5 microphone to the teacher, she pins it on her
6 shirt, and she can pair up to four children in
7 the classroom who have Baha's.

8 There's a TV streamer. So you have the TV
9 streamer just placed right next to the TV, and
10 it streams directly into the processor.

11 CHAR: That's got to be popular.

12 MAEVE: Yes, but you can also use the mini
13 mike for that. You can place that next to the
14 TV.

15 There's a phone clip. So streaming the
16 phone directly into the processor, you just
17 answer on the phone clip.

18 With the mini mike you can also listen to
19 music. You plug in an audio cord.

20 Any other questions on that? I feel like
21 I'm all over the place. Great questions.

22 So who can get a Baha system? Adults and
23 children five years and older. So children
24 don't have enough cortical bone or enough hard
25 bone to be able to osseointegrate an implant.

1 So we wait until they're about five, six, seven
2 years old. Until they have surgery they can
3 wear it on a soft band on their head. So if
4 you ever see kids with a colorful band and a
5 process sticking on it, that's the Baha with
6 the soft band. It can be fit as soon as the
7 baby is old enough to raise their head, and we
8 have lots of little four- or five-week-olds
9 with Bahas on that have been diagnosed with
10 conductive hearing loss at birth.

11 So mixed or conductive hearing loss, we
12 went through this. So the mixed would be a
13 sensorineural component as well as the pure
14 conductive component, and a patient with the
15 mixed conductive hearing loss probably would
16 not do well with the Attract. They would do
17 better with the direct conduction of the
18 titanium abutment, but that's something to be
19 discussed with the ENT.

20 So here is how it works. So the sound is
21 coming in here through the processor, into the
22 processor through the titanium implant, and it
23 completely bypasses the ossicles and goes right
24 to the cochlea. That then sends the signal to
25 the brain. So it's completely bypassing

1 anything in here. So some patients, quite
2 often they'll have to have it redone, and
3 usually after the second failure of the
4 stapedectomy they'll go, "That's it. I'm done.
5 I'll just get a Baha. I can't go through this
6 again." That's when they repair the ossicular
7 chain.

8 And they both work the same, but with the
9 Attract, here is the implant right here with
10 the magnet on top of it. This is all under the
11 skin, and then we come along with the external
12 magnet and the processor attached to that.

13 With the Connect system we have
14 internal -- the implant and then the abutment
15 is percutaneous. That means it's sticking out
16 through the skin, and that's why there needs to
17 be a hygiene routine with the percutaneous
18 abutment, and then the processor attached to
19 that.

20 And so like I said, if you can start off
21 with the magnet and if over time your hearing
22 loss diminishes, you can go in. It's a simple
23 procedure. They just expose the magnet, take
24 it off, and screw on the abutment, and that
25 would probably be about a ten-minute procedure.

1 Hopefully nobody has to go that route. We
2 never want to encourage surgery, but just know
3 there are options if you decide to go with an
4 Attract and down the road you need a little
5 more power.

6 So regain about a 360-degree sound
7 awareness for people who are deaf in one ear.
8 I think we talked about this. I'm not going to
9 rehash what this is all about, but experience
10 sound without anything in your ear. So like
11 you said, Rosemary, you have chronically
12 draining ears, and if you have a hearing aid
13 and just can't wear anything in your ear -- Not
14 to say that if you have a sensorineural --
15 Erin, you might comment on this. Not everybody
16 who has chronically draining ears and wears
17 hearing aid is a candidate for a Baha.

18 ERIN: Depending on how many much or
19 sensorineural hearing loss you have outside of
20 the fluid and infection, that's what really
21 comes into play is how much sensorineural
22 hearing loss you have on top of the conductive.

23 CHAR: So you can be completely deaf in
24 the ear with the Baha?

25 MAEVE: Yes.

1 AUDIENCE MEMBER: You have to have one
2 good ear?

3 MAEVE: Yes. You could get bilateral
4 Bahas and drive the sound to both ears, and
5 that way you don't have the crossover, but
6 yeah, that would -- but that's pretty rare.
7 That's pretty rare.

8 CHAR: You have to have -- Can you be hard
9 of hearing in the good ear and still use the
10 Baha?

11 MAEVE: Again, it depends on the level of
12 deafness in the good ear. We do have a
13 portfolio of processers. So we do have ones,
14 more powerful processers than the Baha Four.
15 We would always try a more powerful processor
16 before recommending any other process.

17 So I had touched on the Baha Four
18 processor and the portfolio of processers, and
19 I've got some of those back there, but with the
20 new Baha Four we have the Ardiium platform. So
21 this is the first time we've actually put a
22 chip into the processor. So with technology
23 coming down the pike, and as things progress,
24 we can upgrade everything on the outside, and
25 that's always our goal, even with our cochlear

1 implant, is that we upgrade everything on the
2 outside and not have you have to redo a
3 surgery.

4 Pure Sound IQ is really nice, and
5 something similar will be coming for the
6 cochlear implant, too, and that's where -- it's
7 got a scene classifier. So the sound coming
8 in, the processor will take the sound coming
9 in. So you could walk from -- I could walk
10 from this room outside to the busy street, and
11 then go to the children's playground, and
12 there's all different sounds coming in, and the
13 processor is going to analyze those and give me
14 the program that best suits that environment
15 for that moment.

16 So you don't have to mess with programs.
17 Like "Oh, I'm going into a bar now. I need to
18 put my noise program on." It does it for you.
19 So it's really, really nice.

20 The true wireless with the mini microphone
21 and the TV streamer, and that's the Resound
22 technology I was talking about. That's the
23 little kit we passed around earlier, and that
24 is available now for the Baha.

25 And data logging, which is -- we also have

1 on the cochlear implant, but that helps your
2 audiologist know how often you're wearing the
3 processor, and if you go to your audiologist
4 and say, "I'm just not hearing well and I'm
5 just not doing well," and the audiologist will
6 look at the software and say, "That's because
7 you're only using it for 30 minutes every day.
8 You can't expect to do well." Or you're
9 spending a lot of time home alone and you have
10 the processor on, but there's no noise coming
11 in. So the brain is not getting used to
12 listening with the technology. So it can also
13 help the audiologist to just figure out what is
14 the best program for your lifestyle, because it
15 tracks like a 30-day -- it keeps 30 days of
16 data. It's not a spy. It's really just to
17 help you.

18 Okay. And again, I feel like I'm beating
19 a dead horse, but this again is the Attract,
20 and it's really exciting for us because it's
21 the first time in many, many years that there's
22 been such an innovation in Baha technology. So
23 we're just really excited about the whole
24 thing.

25 So this is our patient five weeks after

1 surgery. So he's been fit with his processor,
2 and that can be fit at four weeks after
3 surgery, as opposed to the FDA recommends three
4 months to wait for a fitting with the abutment.
5 He looks great. So reduced risk of infection
6 and trauma. If he was to be playing fly
7 football or something, he would just take his
8 processor off and not worry about there being
9 damage done. If he had a titanium -- and
10 that's another consideration for like a young
11 boy who is playing football. You know, the
12 parents would probably want to consider the
13 trauma to a titanium abutment could be pretty
14 painful.

15 And so this is how it's buried under the
16 skin. You see here is the implant, and then
17 the magnet sitting right on top of it. So
18 there's no soft tissue reduction. It used to
19 be back in the day, if any of you know someone
20 with a Baha who may have -- who was implanted
21 maybe four or five years ago, there's a big
22 divot in the back of the head and a bald spot,
23 and right in the middle of it is the abutment.
24 We don't do that any more. The surgeon doesn't
25 take any soft tissue out, doesn't cut the hair

1 follicles. So the hair just grows back like
2 you saw on that gentlemen.

3 AUDIENCE MEMBER: How does that actually
4 go into the skull then?

5 MAEVE: It's drilled in.

6 AUDIENCE MEMBER: The piece we were just
7 passing around?

8 MAEVE: That part sits on top. It's just
9 used with a screwdriver. It's just attached
10 with a screwdriver.

11 Here is the implant. It goes in the bone
12 right here. It's drilled in just like a dental
13 implant. It's four millimeters. It's like
14 that deep.

15 AUDIENCE MEMBER: I thought the round
16 piece went in my skull.

17 MAEVE: No. The four millimeter implant,
18 it's placed just like -- We use a dental drill.
19 So the procedure hasn't changed from back in
20 1977 when it first came out. So it's tried and
21 tested, and then so that sits in the bone, and
22 then this is just screwed down on top of it,
23 and there's an orientation for the magnet that
24 the surgeon takes care to place the magnet
25 facing up, with the arrow facing up. So then

1 when you put the processor on, it just
2 attaches. Otherwise it would fling it off.

3 And then we've got these soft pads on the
4 magnet, and I'll pass this around. It's like a
5 memory foam, and also -- well, it disperses any
6 pressure you might feel from the magnet on the
7 skin. So it doesn't break down the soft
8 tissue, and this all comes from what we know
9 about cochlear implant magnets. These can be
10 replaced once they start to wear down. You get
11 like two years worth of these with the
12 processor. So I can pass that around and you
13 can feel it. They just peel off.

14 AUDIENCE MEMBER: Does insurance cover
15 anything that you get later, like new
16 technology?

17 MAEVE: It depends on your insurance.
18 Medicare covers anything that's necessary for
19 the function of the equipment. If it's a
20 nice-to-have, it's not needed but it's nice to
21 have, Medicare won't -- typically doesn't pay
22 for it.

23 And the magnets come in six different
24 strengths. So the patient will get a couple of
25 different strength magnets because any time

1 there's surgery there's swelling. So you
2 probably need a stronger magnet right after
3 surgery, and over time the swelling goes away
4 and the soft tissue flattens out. Certainly
5 you don't want to stay with a stronger magnet
6 if you don't need to, but you'll know.

7 CHAR: Over time, even with the weaker
8 magnet, and that would be the Baha or cochlear
9 implant, is your skin getting thinner and
10 thinner over time?

11 MAEVE: No, not if it's the right strength
12 for you. Now, sometimes with the cochlear
13 implant magnet, you know, the audiologist sets
14 it to where it needs to be in the coil and, you
15 know, if you're like -- it's not staying on,
16 you need to go back to the audiologist, rather
17 than trying to tighten it yourself and push it
18 closer because if there is skin breakdown, it
19 can cause the implant to extrude, and you don't
20 want that. That's pretty miserable.

21 I just met a lady who was -- She just got
22 her implant maybe three months ago, and she
23 started to have skin breakdown because her
24 magnet's too strong. So she has to keep it off
25 for a few weeks and let it heal and then get a

1 weaker magnet. It's very important that you
2 check it or have somebody check your magnet
3 site. Same for this. If there's any redness
4 or swelling or discomfort, take the magnet off.
5 Something's not right.

6 All right. And again the wireless, we've
7 talked about this. It's easy to use. It's
8 paired just like you pair a cell phone, a
9 Bluetooth to a cell phone. So once it's paired
10 it stays paired unless you unpair it.

11 With the streamer, the TV streamer, if you
12 leave the room, your processor -- if you come
13 back within 15 minutes, it stays paired. If
14 you leave and you're gone for like 30 minutes,
15 you have to re-pair it when you come back in,
16 but it's very simple and straightforward. The
17 feedback on this has just been phenomenal.
18 It's nice not to have any wires or an
19 intermediate have to wear a ComPilot or
20 something around your neck.

21 And it comes in blue. Kids just love
22 this. There's a whole bunch of colors, and
23 it's amazing what you'll do to get your kids to
24 wear their processor, but they can decorate it,
25 they can bling it. They can get a skin with

1 their Frozen characters on it. They can do
2 whatever they want just to make them wear it.

3 So this was the BP100, and you're
4 probably -- I don't think anybody here has a
5 Baha, so you're not familiar with it. So I'll
6 just skip through it. It looks the same and it
7 functions the same.

8 Some of the buttons, we had gotten
9 complaints about where the buttons were. So we
10 updated that, and hopefully coming by the end
11 of the year we'll have a new processor that is
12 a bit smaller, and we'll have some exciting
13 technology in there.

14 CHAR: Even more so today, people think
15 the technology is changing so fast, the
16 processors are getting so much different, you
17 almost want to put it off so that you get the
18 best processor, and then of course that never
19 ends, and of course Medicare and others,
20 they're not going to pay for it.

21 MAEVE: With the Nucleus Six, the nice
22 thing is that processor is not going to be
23 replaced any time soon because there's so much
24 headroom on that processor that all new
25 technology will just be a software update at

1 your audiologist office.

2 ERIN: There's a push for that in hearing
3 technology anyway, to minimize having to
4 replace the actual device and upgrade it just
5 by hooking it up to the computer, similar to
6 your iPhone or any smart phone. You put a new
7 app on it or you upgrade the software instead
8 of upgrading the whole thing.

9 CHAR: And someday again, the holy grail,
10 it's all going to be inside. There will be
11 nothing external.

12 MAEVE: Right, and we are working on that.

13 CHAR: Oh, boy.

14 MAEVE: The totally implantable cochlear
15 implant.

16 AUDIENCE MEMBER: When you talk about in a
17 few months a newer version, like it's approved,
18 three months, four months?

19 MAEVE: Hopefully by the end of the year.
20 When you're working with the FDA it would be
21 remiss of me to try and put a time frame on it,
22 like say it will be in December, because
23 December somebody will call me and say, "You
24 said it was in December," and six months later
25 the FDA still hasn't approved it. That's what

1 we're hoping for. It will be a new design, but
2 the functionality will still be the same.

3 AUDIENCE MEMBER: You touched briefly on
4 directionality. I wear the Nucleus Five and a
5 Resound hearing aid, and when somebody speaks
6 in a room, I'm looking around because I have
7 trouble figuring out what direction. Is the
8 Nucleus Six better at acknowledging or picking
9 up where the sound's coming from?

10 ERIN: Your brain, so with two of the same
11 device, your brain can figure that out. So
12 it's all about how the brain is interpreting
13 the signals in time. So we're talking about
14 microseconds. So if you hear a sound from over
15 here, it's going to hit this ear first and hit
16 this ear second, and your brain can detect a
17 very tiny difference in microseconds. That's
18 how we tell with two normal hearing ears or two
19 ears with hearing aids or two ears with
20 cochlear implants. So when it's two different
21 types of stimulation, acoustic and electric,
22 your brain has a much more difficult time
23 figuring it out. So localization is something
24 you do best when you have two of the same
25 device. So a hearing aid and a hearing aid, a

1 cochlear implant and a cochlear implant.

2 AUDIENCE MEMBER: It doesn't matter if I
3 upgrade to the Nucleus Six? I'm still going to
4 look around?

5 ERIN: Probably not. However, the Nucleus
6 Six has technology in it like -- available like
7 a mini microphone or something like that you
8 can give to someone so you'd be able to hear
9 their voice above all the other noise. If
10 you're out and not using those extra
11 technologies, you're still going to have to
12 look around. Usually if it's directly over
13 here or directly over here, you can probably
14 tell, but it's the finer differences.

15 MAEVE: But the nice thing about your
16 Resound is if you had the wireless, it will
17 pair to both.

18 CHAR: We're almost out of time. No
19 pressure.

20 MAEVE: And this is just some of the
21 benefits of the Baha Four processor. Spectral
22 bands, which is really only audiologists are
23 interested in.

24 Feedback analyzer. There's always the
25 problem of feedback with hearing aids, and

1 we've heard it in the room this morning, but we
2 did have an issue with the BP100 and feedback.
3 So we've taken care of that with an analyzer.
4 So we run -- the audiologist runs a quick
5 program on the processor when you have it on,
6 and it just analyzes where feedback could
7 potentially be and gets rid of it.

8 The scene classifier is what I talked
9 about when you walk in a room and it
10 automatically adapts your hearing environment
11 to the processor.

12 The noise manager, same thing.

13 And then for any golfers or bikers out
14 there, it has a wind noise program. So between
15 the two microphones on the processor it figures
16 out if it's not speech that's coming in, then
17 it must be wind, and it cuts that down.

18 So I'm done. Perfect. Yes?

19 AUDIENCE MEMBER: Just like any
20 specialist, do audiologists specialize in the
21 Baha?

22 MAEVE: A hearing aid dispenser can
23 dispense the Baha, too. So it doesn't have to
24 be an audiologist.

25 DOLLI: A hearing aid dispenser is an

1 audiologist.

2 AUDIENCE MEMBER: Some hearing aid
3 dispensers are better than others.

4 MAEVE: Of course.

5 ERIN: You don't have to be an audiologist
6 to be a hearing aid dispenser. Anybody can get
7 a hearing aid dispensing license if they take a
8 test at the state. An audiologist has a
9 doctoral degree in the science of audiology.
10 So they can be very, very different. There are
11 some good hearing aid dispensers out there, but
12 they're basically salespeople. So you have to
13 be -- but there are some good ones. So there
14 are some good audiologists that specialize more
15 in Baha.

16 MAEVE: And we train. We don't just let
17 somebody dispense our product without giving
18 them full training.

19 All right. Any other questions on the
20 Baha? Thank you. Great.

21 CHAR: I've learned so much today. It
22 hurts my brain to take it all in. So that's
23 it. It was a great meeting, and we'll just see
24 you next month.

25 MAEVE: I just wanted to take this

1 opportunity, if anybody in the San Diego area
2 would like to come and meet with other cochlear
3 implant recipients who have this device or the
4 Baha, we meet once a month, and so if you want
5 to give me your contact information, I will
6 send you the invitation for the next meeting.

7 (End of meeting.)

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