Multi-Jurisdictional Micro-Invasive Glaucoma Surgery (MIGS) Contractor Advisory Committee (CAC) Meeting Transcript January 5, 2023

Dr. Lisa Banker
I have just started the recording of this CAC meeting and in compliance with CMS. For the record, prior to doing so, I did announce that Palmetto GBA would make an audio recording of the CAC meeting and consented on behalf of Palmetto GBA.

So, I believe we're ready to go. Thank you so much for all of you being here.

Our first questions have to do with general MIGS procedures, if you could help enlighten us a bit. So, my question to all of you is, how do you define failed medical management for glaucoma and when does it warrant a MIGS procedure?

Why don't I just start with Dr. Sola-Del Valle, if you would.

Dr. David Sola-DelValle
Hi Lisa, how's it going? Can you hear me?

Dr. Lisa Banker
Yes, I can. Thank you, David.

Dr. David Sola-DelValle
Yeah. I think Geoff and the group met and decided we're going to try to tackle the questions and talk to certain questions at the end. Pradeep is going to take this one.

Dr. Pradeep Ramulu
Sure. Yeah. No, I'm happy to take it. So, thank you for having me. Failed medical management can refer to either a pressure which is elevated, which risks further glaucoma progression or evidence that glaucoma progression is happening with the medications maximally used. In other words, that all medications or nearly all of the medications that could have been tried on the patient have been tried.

You know, when does it warrant a mixed procedure? I mean, that's a very complicated question. I mean, I think the question itself, you know, first of all, is maybe a little bit kind of implying that MIGS procedure is only warranted when there's failed medical management. I would say that, you know, that there is evidence that from the Horizon trial that pressure is lowered surgically with one of the mixed devices and that trial actually prevented glaucoma progression better than the same pressure that as measured clinically by cataract surgery alone, and medications indicating that probably surgical control is actually controlling pressure in a more consistent basis and so there is evidence for better visual field control with MIGS and prevention of glaucoma damage.

You know, when does it warrant a mixed procedure? I mean, that's a complicated question. It depends on whether those coexisting cataract. It depends on at what rate the patient is progressing. It depends on the severity of disease. It depends on the kind of their comorbid conditions, including what systemic medications they're on. It depends on the status of the other eye and how that eye has is in terms of its severity of damage and how it's responded to various therapies. With medical and surgical depends on the type of glaucoma, whether it's open angle or closed angle.

I'm not trying to be evasive, it's just, you know, I think the answer is just highly dependent on the individual factors for the patient. And so, it's really hard to kind of give you a straightforward, simple answer of exactly when a MIGS procedure is indicated or not.

Dr. Lisa Banker
OK. And who else did we have that was going to weigh in on this one?

Dr. Emily Jones
This is Emily Jones. I was going to weigh in on this one, too.

Dr. Lisa Banker
Hi, Emily.

Dr. Emily Jones
Hi. But did you have a follow up question?

Dr. Lisa Banker
I'd like your take on this as well. Unless you had anything more specific to answer to that.

Dr. Emily Jones
I think Doctor Ramulu answered it very well. As far as when you would use a MIGS, he was mostly comparing it to and continuing to manage a patient on medical therapy, and I think maybe the one point he didn't explicitly touch on is that the MIGS procedures overall are considered to be much safer than traditional glaucoma surgery, things like tubes and trabeculectomy, which used to be our only option for patients who weren't tolerating medications or who showed evidence of progression on their medications and have a very significant risk profile. The MIGS procedures in general are much safer for patients with a lot less potential for vision threatening complications.

Dr. Pradeep Ramulu
Yeah. If I could maybe expand in my prior answer a little bit, too. I mean, there's maybe, you know, two big areas where things are used. One is, you know, a stand-alone procedure where maybe then you are doing it when you're not happy with the medical treatment of the patient, and then also when another surgery has already indicated, typically when cataract surgery is already indicated and then you're considering a MIGS device, you know, with the evidence that we have from the Horizon trial, everything it's become very appealing and almost the standard of care that a patient be offered MIGS procedure at the time of cataract surgery, if they have manifest glaucoma, or if they have very high risk of glaucoma progression, even if they don't have manifest glaucoma right now. The standalone is maybe a separate question, you know, because then it depends. This specific question comes more into play, you know. Are you happy with the medication control or not? And then, you know, do you really want to do a stand-alone procedure? So, just to clarify that this question, maybe you ought to be broken out into the stand-alone versus combined procedures.

Dr. Lisa Banker
Right. And I think we're going to touch on that coming up a little bit. I was going to ask, what makes you not happy with medical management?

Dr. Michael Repka
So, this is Michael Repka. I'd actually liked to weigh in on that, and I think the thing is medical

management can be a burden for many of these patients getting one, two, or three drops a day. And where the MIGS can reduce that additional treatment burden for the beneficiary, that's a real save because at the same time, it's doing more for level control. And in fact, they probably get the treatment as opposed to not getting the drops all the time.

Dr. Geoff Emerick
Right. All right, this is Geoff Emerick. Just wanted to comment a bit on the definition of failed medical management that ties in a bit to our proposed definition of refractory glaucoma. The AO, Astros and AGS wrote a letter that relates to FDA endpoints and regulatory assessment of devices. So, we defined, we would, we proposed the definition of refractory glaucoma as when the IOP is above target values that the clinician has chosen to slow or halt disease progression despite the use of either multiple classes of medications or fewer medications. When tolerability or effectiveness limits the use of those classes and that's often the case where medications are not tolerated or there are contraindications, or they're of limited effectiveness. I just wanted to add that.

Dr. Lisa Banker
OK. I did have sort of one other question along those lines. It strikes me that the medication burden makes some sense as far as the reduction of that medication burden, as far as measuring some sort of tangible outcome for a patient. But what about IOP measurement?

You know, I think there's been some argument over the years that it's almost more of a symptom of glaucoma at times and that it doesn't; it's almost as more of a proxy, but not really an actual outcome. You know, as far as actual vision loss or blindness. Just wondering if someone could comment on that.

Dr. Pradeep Ramulu
Yeah, I would say that is true to some extent, I mean, but I think we're in the game of prevention. So, you know, when the pressures are, I think we are projecting the future and when we see a pressure that we think is dangerous for somebody, you know, we base on clinical studies, we will often act prophylactically to try and lower the pressure to prevent vision loss. I mean, you can argue that while you should wait for that person to lose some vision, but then, you know, even if they've lost two or three decibels of vision on the visual field, that person reads slower and is more likely to fall and is more likely to have to stop driving or limit their driving. So, their life is already affected. So, it's a balance where there are certainly many instances where you want to treat prophylactically so they don't have that impairment. And I think that is more often the case in with MIGS procedures because they're so safe.

Dr. Karen Allison
Yeah.

Dr. David Glasser
I would like to just add a little bit of emphasis to what Dr. Pradeep said. This is David Glasser. You know, it's not just most of the time. I mean the entire goal of glaucoma treatment is prevention. When the vision is lost, you don't get it back. It's not like a cataract. You can't fix it. So, it's true that IOP may be a symptom, but it's what we have as our early warning sign, and there is a little bit of you might call it guesswork. We might call it experience in determining, you know, what is a safe pressure for an individual patient. The problem is that there's no single answer that applies to all patients or even subsets of patients. Each patient is individual. So, we're really in the business of preventing vision loss

here and things like getting the pressure down to what we think is a safe zone or reducing the patients drop burden. So, we have greater confidence that they'll be able to adhere to the drop regimen, are very important aspects of the treatment of glaucoma and it is complicated. It's not something that easily fits into a flow diagram.

Dr. Emily Jones
Can I add on to that, Lisa?

Dr. Lisa Banker
Yes, go ahead Dr. Jones.

Dr. Emily Jones
As a glaucoma specialist, the way that I think of it, and I think the way I explain it to patients, is that we are well aware that pressure is not the whole story. In glaucoma, it is the most significant known risk factor for glaucoma progression and it's the only one that we can control at all. So, we treat pressure because that's what we have. But you're absolutely right, it isn't glaucoma does not equal pressure and vice versa. But that's treating glaucoma is our entire strategy and preventing vision.

I'm sure you know that we can have patients who have 20/20 vision and are legally blind because the vision, like visual acuity, is the very last thing to go in most cases in glaucoma.

Dr. Karen Allison
Yeah, this is Dr. Karen Allison. I just wanted to point out another issue is that these procedures actually help to equalize the treatment of glaucoma for a big subset of patients that are not responding as well. These are African Americans and Hispanic patients that have about one-third of blindness from this disease. So, the fact that we can give them another alternative, such as a mixed procedure cataract with MIGS has shown that this this definitely allows the decrease in pressure for significant time until, you know, for at least two to three years. So, this group of patients, definitely this is A-plus for them. Not to say it's not good for everyone, but this is a group of patients that we finally have something that we know will help them to decrease the burden of the disease and especially patients that are not as compliant with their medication. I think when we look at the data in a few years from now we'll see that the projection of blindness for African Americans and Hispanics will be less with the benefit of this procedure.

Dr. Lisa Banker
How have how have we done over the last decade or two? I mean, MIGS procedures. There's a whole variety of them. There's been burgeoning various medications added over the decades, lots of new procedures, and yet every glaucoma study I read starts out the same way, and that is the glaucoma is the leading cause of visual field loss. But how come? That never seems to budge. How come that's always the conclusion, despite all the additional therapies? I see everyone giggling and laughing, but help us understand that.

Dr. Pradeep Ramulu
Well, I mean, it's always going to be the most prevalent cause because it's just a highly prevalent disease. And you know, there are data for example from the Mayo Clinic which did two consecutive series of prevalent studies and a very contained area which did show that the rate of blindness from glaucoma did go down. Maybe not a current enough one to really look at MIGS but if you look at an

older period in the 70s and 80s and then another period in the 90s and early 2000s that the prevalence of glaucoma, blindness did go down.

Dr. Lisa Banker
So there's no current evidence along those lines.

Dr. Pradeep Ramulu
No, but it's, you know, there's plenty of prevalence studies, but to really, you know, have an apples to apples comparison within a similar population there's no clear evidence of that. I mean, no.

Dr. Lisa Banker
OK.

Dr. Geoff Emerick
And we're better at detecting glaucoma early. We have structural measurements that can detect even a very early structural changes long before there's vision loss, whereas in the past, people we waited for vision loss before you started treatment were able to start treatment earlier. So, there's many more people being treated. The morbidity has gone down. The effectiveness has improved. So, more people are being treated earlier. On the other hand, people are living longer and there is inevitably then an increased prevalence.

Dr. David Glasser
Yeah.

Dr. Lisa Banker
What are the absolute very best studies that show that this preventive prophylactic emphasis gets us somewhere that we actually see patients with less visual loss or with less blindness are there are there classic milestones, you know, evidence-based documents that show that this prophylaxis emphasis really gets us anywhere?

Dr. Karen Allison
Definitely. The upper hypertensive study shows that if we decrease the pressure by at least 20 percent, that they it will decrease the patients that will go on to get glaucoma. So, if we if we treat, and especially if we treat aggressively, maybe even more than 20 precent, it will definitely decrease the amount of patients that will go on to get welcome, and therefore blindness while comments is to slow the progressive disease. So unfortunately, it will take years for us to see the benefits of a lot of these procedures that we're doing. That's the reason that we have to continue to do that and 10 years from now, we will definitely see the benefit.

Dr. David Glasser
You know that a historical perspective, we treated glaucoma for approximately a century before we're able to demonstrate with that ocular hypertension study that lowering pressure actually reduces blindness and vision loss. We all knew it was true, but we couldn't prove it with an RCT until that very large, well-funded long-term study was published. And now that we have 87 different treatments for glaucoma, trying to do comparative studies with multi-year follow up because glaucoma generally is a slow moving disease is basically an insurmountable task.

Which leads me to another comment and maybe it's too early for this, but I think we need to keep in mind that some differences in instruments that accomplish the same thing anatomically may be less important than we might be led to believe by the manufacturers of those instruments who want us to believe that their gadget is the only one that can do this well. So, when we see different techniques for doing the same thing, I think it may be unrealistic to expect big long term studies comparing them. You know, you can take out a cataract with extracapsular surgery or fake or emulsification or with the femtosecond laser and you're anatomically end up with the same result. And I think the same thing can be said about, you know, removing the trabecular meshwork and opening up Schlemm's canal. There's a lot of ways you do it. You can do it from inside or outside or with this blade or with that blade. And you know, I joke about with a grapefruit spoon, but if the result is the same, the results are the same.

Dr. Michael Repka
OK. And I think it's going to be getting understood.

Dr. Lisa Banker
OK. And you're right. I think we're going to be getting into some of that when we speak about the students.

The second question, if you're following along here, I think we already sort of addressed what factors influence selection of one MIGS procedure over another. And I think the general consensus was that it is too complicated, and it depends, it is sort of what I heard. And then the third question for both Goniotomy and standalone stent procedures, what evidence exists that speaks to durable long term outcomes? And again, I think we just sort of addressed that where you were. I'm sure we're going to talk about this several times tonight, but you took me back to the OHSU study. I think that's what you all were saying. So that's something that we'll have to look at very carefully, obviously.

So, let's move into the stents as stand-alone procedures. Our first question there was do you think there is sufficient evidence to support placement of stents outside of cataract surgery for POAG?

Dr. Geoff Emerick
Right. So, this is Geoff Emerick. So, there’s multiple studies that support the use of these stents as effective, safe, and effective IOP lowering procedures. The [inaudible] study looked at standalone Hydrus versus two stents in mild to moderate open angle glaucoma, about half of those patients, or two-thirds, were fake. But the washout IOP in the high 20s and they're 12 month complete success rate which meant no repeat surgery pressure less than 18 on, no medications was 30 percent in the Hydrus group, 9.3 percent and the iStent® group. Those percentages were a bit higher in pseudophakia at the end of the 12 months, patients were medication free, patients were 47 percent in the Hydrus group and 24 percent in the iStent® group. There was a decrease in medications from one to two meds decrease and that was probably the most impressive result was the ability to significantly decrease the medication burden.

The CATS study randomized patients to one, two, or three stents. Most of those patients who are fake at 42 months, so good long term data there, their medicated pressures were about 15. IOP reduction as Karen mentioned of greater than 20 percent without medications and 61 precent with one stent and 91 percent in two or three stents. And even when you wash them out of all pressure lowering medications, that 36 month pressure remained 15, 14 in those two or three iStent® group.

The Circassian study, the pivotal trial for the iStent® infinite, the three stents 76 percent greater than 20 percent reduction on the same or fewer meds. IOP change of six, and many of those were fairly complicated patients, so 84 percent had failed one or more prior incisional surgery. So, even in those fairly challenging patients, there was a very good results there.

And then the last one would be Rob Fechner study which showed five year results of standalone stents. Two stents versus medication with travel, Prost and at five years pressures were equivalent, but much less need for add on medications. So ,at the end of the five years, 77 percent of patients in the iStent® group did not require addition of any medication. So, that's kind of what our patients are looking for is to not have to take drops every day and that was achieved in that group.

There's been there's a meta-analysis that Healy published in 2021, including four randomized trials and nine single arm studies, 778 eyes with the mean IOP reduction of 30 percent at 60 months. So, I think a lot of data pointing to good, safe, and effective long term IOP control with these devices.

Dr. Lisa Banker
But again, really new studies. So, we're talking about IOP control, but we don't have anything that tells us where people are going to be years from now with standalone stents or anything to support that.

Dr. Geoff Emerick
Right. Although there is a great deal that shows that if you control pressure that you decrease the risk of vision loss. And if you control pressure, perhaps using stents as the Horizon study showed that equivalent pressure lowering with a stent versus medications, there was half the rate of visual field loss in patients who had the stent. And thinking there is more stable IOP, less peaks and troughs, less reliance on medication adherence, and a variety of other factors. So, we do have some I think good evidence that lowering pressure with surgery is better than lowering pressure with medications in terms of patient outcomes.

Dr. David Glasser
Geoff, what if the question we're asked like this in an ideal world, how long would it take to demonstrate a significant difference in vision loss by field or by comparing these two things and if we weren't able to offer those procedures outside of a randomized clinical trial during that period while we were waiting for the results, how many people would go blind in the interim?

Dr. Geoff Emerick
Right. Good point. You know, if that's five years then that's a long time for those patients to wait.

Dr. David Glasser
You know, my concern is that it takes a long time even if you can get the studies done to demonstrate that that difference in actual outcomes. And we have so much evidence in the past that lower pressure equals less vision loss that it seems like reinventing the wheel to have to prove that again and again when it's easier and faster to show the reduced IOP or the better compliance with the drop regimen. So, I think I would argue for you now using that proxy rather than waiting in terms of making coverage decisions.

Dr. Lisa Banker
Do any of the other Contractor Medical Directors want to weigh in at any point here? I just want to make sure that opportunity is out there. OK, I think they're in listening mode.

All right. Was there anyone else that wanted to weigh in on that?

Dr. David Sola-DelValle
I mean, we mentioned the old study, but two studies that I also use to justify lowering IOP are the Ages study and the CNN TGS study. I feel like that also shows that lowering pressure I mean for instance advanced glaucoma patients who live in a pressure in the low teens do much better in terms of visual field loss, that patients who live in the high teens and above 18C NTGS showed that for those normal tension glaucoma. Patients where we can lower pressure by 30 percent, assuming there are at a high risk of progression we can actually slow progression in those patients. So, there's at least three if not more of randomized clinical trials that have shown that pressure. You lowering pressure does equal stopping or slowing the progression of the visual field. And I agree with David Glasser the other David who was saying, you know, using the OPS proxy I think is justified given that we do have high quality data and evidence showing that lower IOP means less vision loss and less blindness.

Dr. Lisa Banker
So for those of us who obviously aren't Ophthalmology-based, how is vision visual field loss best measured and what is sort of the broad milestone that you're looking for in terms of reducing the rapidity of vision loss and the quantity of it?

Dr. Pradeep Ramulu
I can answer that. Basically, you're looking at on average, you know, how much brighter do lights need to be shown to a person for them to be seen across their field of vision. So, in other words, they're losing sensitivity to stimuli that they would detect in their peripheral vision. And also, they're fairly central vision as well. And so, we, you know, we have a metric, it's called the mean deviation. So, in other words, it reflects on average how much brighter do things need to be shown and it's on a decibel scale because it's logarithmic. You know, it's a complicated scale and we don't really need to get into all the details because it's going to be lost. But, you know, the scale goes from about 0 to -30, and if you lose even one or two of those decibels along that it's not necessarily catastrophic, but it does affect you. I have a slide which I could share, which, you know, shows that you read a couple of words per minute slower. Your chance of falling goes up by about one or two percent. Your chance of stopping driving goes up by one or two percent. You know, you walk slower, you leave your home less and so for each individual person it may or may not be catastrophic. But when you talk about thousands or tens of thousands of people who all function a little bit worse it's a drain on each of them and it affects the society, and it affects all of us in different ways. So, you should really think about it as individual people are going blind. It's a lot of people functioning worse.

Dr. Lisa Banker
Right. Well, again, I just asked because as you look at these studies and see these things you want to try and make sure you're interpreting what you see on the visual field changes appropriately, so that's why I asked.

So, our second question here is what should be done in a patient with both cataract and POAG? For what type of patient will cataract extraction alone be sufficient? Is there someone who would be appropriate for just cataract surgery alone? In other words, what makes you decide to do something additional?

Dr. Elyse McGlumphy
I can start with this question. In any patient that has open angle glaucoma and a visually significant cataract, I think we really owe it to them to offer them a MIGS procedure. You know, there's such good data. You look at the Horizon study and we have evidence that MIGS slows the field progression, it cuts it almost in half and those patients and will lower rate of visual field loss. And so, I think, you know, in a patient on any therapy or a patient with glaucoma, you really owe it to them to offer them a MIGS procedure. I offer this to every patient with glaucoma. The primary opening with glaucoma and patients that might be cataract extraction alone would be sufficient. I mean, this gets into a really complex area. I think, you know, if you're looking at primary angle closure, you could consider something like that, but you wouldn't want to exclude these patients from having MIGS as well because depending on what their angle looks like and the amount of damage, you may want to offer them something as well. So, it's really patient dependent and it's hard to develop hard and fast rules for these things, but definitely for my open angle glaucoma patients, I think we have sufficient data to say that it's it really does them a great benefit.

Dr. Geoff Emerick
Yeah, I would agree with that. There's good data that countered surgery alone will transit transiently lower IOP by a point or two. But really over the long term does not decrease medication burden. And that at the time of cataract surgery that's that is a good opportunity to be able to treat their glaucoma as well. And I agree, if you're diagnosing them with open angle glaucoma, then all those patients would be candidates for MIGS procedures angle closure. Glaucoma is of a different story and as you mentioned, Kettering extraction can be a treatment option for those patients but not for open angle.

Dr. Lisa Banker
OK. Any other comments or questions from anyone on the line?

All right. I was going to blouse over the next question, but I I'm going to actually ask it now because y'all seem to be awfully united. I'm not getting too much variability here on thoughts or anything.

Reviewing the evidence, all these various pieces of evidence that have been mentioned, particularly some of the recent things and the pivotal trials and so forth, do you guys as practicing Ophthalmologists have any concerns or any thoughts that there's any bias to these studies? I know we often see that the manuscripts have been helped along, not helped along, but have been, I don't know what the right word is to use, but the various device manufacturers have contributed to the manuscript creation, etc. Just any concerns along those lines from practicing physicians.

Dr. Michael Repka
Well, let me generically jump in and say that I think all of us practicing Ophthalmologists care about how a study was conducted and it is a red, but not necessarily a red flag, but a warning that a study that's completely industry supported and industry wrote that paper and the conclusions could represent bias and it is incumbent upon those of us that are on editorial boards to identify that wherever we can, but also to teach our trainees that these are situations that they really have to be aware of and you're suggesting that, you know, payment side, you have to be aware of it. And so, we are I think that we really would prefer to see all of the studies done without industry support. It would be a wonderful world, but you couldn't do the studies of so many of these medical innovations without industry innovating and without our member doctors creating some of these devices. So yeah, I think it's a warning, but it's one that we have to work through, not one that we simply say is we can't go there.

Dr. Geoff Emerick
Right. And the way that these are conducted, they are done by reputable people in multiple centers. The pressure measurements are done in a way where one person measures the pressure, and another person reads it. So that eliminates some bias. You can't mask the observers to what intervention was done but visual field outcomes, for example, that's entirely driven by the patient. You really can't fudge that. Uh, so I do think we look carefully at these studies and analyze them critically. There's certainly ways that you can make things look good for your desired result. I would just give an example of one study in your bibliography was comparing iStent® injects versus trabeculectomy for example, and trabeculectomy is kind of made to artificially look worse because suture lysis is counted as an intervention and that counts as a failure. Well, that's kind of something that we normally do in the chorus of the postoperatively after a trabeculectomy so again, it just one example, but I think we are looking critically at who's writing these papers. Where are they done? Some of them are ex US. So, we take all that into account.

Dr. Pradeep Ramulu
I would make a couple of comments. I mean one is that with the major industry sponsored trials that showed effectiveness of MIGS in conjunction with cataract surgery it was rather striking that there was a lot of similarity in the results of the control group, the cataract group across all three of those studies. The side PATH study, the iStent® study and the HYDRA study. So, you know, while certainly we do worry about bias and all of those, whereas Dr. Repka mentioned funded by industry because they really have the money to carry on a huge study like that for multiple years, you know, the results for the control groups for all of them was remarkably similar. I'd also mentioned that sometimes you wonder, we always assumed that bias would be in the direction of the device doing better but we don't necessarily know that to be true either. A lot of times these were people who were, you know, using early generations of some of these devices and people who weren't as knowledgeable. And I think we're all getting better at using these devices and knowing how to do them better. And so, it's not clear that all the bias is in the wrong direction. We don't know that to be true.

Dr. Lisa Banker
All right. Question 4 on here was actually included in the first question to some degree. Does anyone have anything additional to answer? I think this is kind of a key question for a lot of us. Is that why to this point, the studies have supported stenting only in a patient demographic with cataract surgery? So why are they now profoundly acceptable as standalones, and how strong is that evidence actually there for that because it is fairly limited evidence again because this is such a new indication with particularly the iStent® that's just received FDA indication for standalone.

Dr. Michael Repka
I think the history is that the companies saw the opportunity to apply to the FDA for licensing authority in the combined setting first and the agency sent them in that direction. And so, they were done as the initial trials perhaps because they were having surgery. I certainly wasn't working in the agency at the time to say why they pushed in that direction but there's history there of how the regulatory process sent industry. The catch-up has been of trouble for me as the CPT® advisor. We want to keep moving these codes into Category I, but the evidence has been behind on the standalone and that's presented a problem for the practitioners because that's not the people they want to use it in much of the time and the glaucoma specialty practice. So, I'll say that's what I know from the history of why we have this order for licensing indications now. As far as I know, everyone in this space is going after a standalone

indication and are working on trials to do that. You know, even the companies that have just coming on to them into the market, this is where they're going now.

Dr. Lisa Banker
And I would think that be very, you know, welcome to all of us because, you know, as you alluded to earlier, Dr. Repka, you know, from the payer standpoint, we're trying to make decisions based on evidence and evidence-based medicine. And yet the evidence is lagging. You know, it's not catching up. It's not very voluminous. it just seems that the evidence basis is often kind of sparse, and I've particularly noticed this looking at all sorts of other pieces of areas of medicine. That seems to be a consistent, I don't want to use the word problem, but a consistent finding in the Ophthalmology sector. That the evidence is often lagging, sparse, small subject numbers, things like that. I don't know if y'all have any comment on that. You know, I know at times I've seen it where people have kind of said, why don't Ophthalmologists really campaign for much more rigorous, extensive studies.

Dr. David Glasser
Yeah, I can comment on that. First of all, I don't think that's necessarily true. Throughout our specialty it varies quite a bit amongst the subspecialties and amongst the well, retina, for example. DRCR network has done an amazing amount of work on intravitreal injections, but I share your frustration in some other areas with common diseases like dry eye where you ought to be able to compare blepharitis this treatment to that treatment and I while I share your frustration, I also share a little less enthusiasm for being a slave to evidence-based medicine, so not every patient behaves according to the mean of a randomized clinical trial. So, you know, five percent are going to be more than two standard deviations from the mean. Significant them are going to be more than one standard deviation from the mean. And people aren't widgets, you know? There aren't 2000s of an inch tolerance like when you're building a car. So, I don't mean to throw evidence-based medicine under the bus. It's hugely important. It guides us. But these are all results that are derived from populations of patients. And when you try to apply coverage decisions to individual patients, there's a disconnect there because the results of a large study tell you what the odds are in a population. They don't tell you how an individual's going to respond. So, I think they're extremely important. But they're not the be all and end all for the individual patient. But that's not to say that there isn't a possibility of randomized trials and not theology. I don't know why there are more of them, maybe because we haven't been forced to do more of them by coverage limitations, I don't know.

Dr. Lisa Banker
Yeah, I appreciate that answer. Thank you for that because, you know, short of evidence-based medicine we do live in a world, you all probably see it less than we do, perhaps, but I know the Contractor Medical Directors and so forth, we do live in a world where some people take a lot of latitude with things, and it becomes very monetarily advantageous. While you're in there doing one thing let's do the other thing too, because it's another. And so, we're always trying very hard to find out what the evidence is to support doing the other thing. You know, and is that an acceptable way to practice. What are the parameters, what are the guardrails that delineate those things? And it's very difficult.

Dr. Pradeep Ramulu
I would add that the space is changing so quickly too. You know, as evidence from this discussion here, there's no multiple implants, there's multiple other ways of lowering the pressure that are not implant

related. And when it changes that fast, it's very difficult because you're not talking about two groups you might be talking about five to six different options. And to really do all the pairwise randomized trials or to do multiple group randomized trials is extremely difficult and extremely expensive and by the time you're done there's going to be new options out there. And so, I think that's challenged us to come up with good evidence. And if you look at the treatment trials that we've done, it's often been when the field was moving very slowly, and it was obvious what the treatment options were. Laser versus medicines, two versus trabeculectomy. And now with things like versioning, it's become a huge challenge. So, I think we want that evidence, and I would very much welcome it. But you know, when you start trying to say, well, how can we tackle getting that evidence when there's so many options, it becomes very, very difficult.

Dr. Lisa Banker
OK. Our next question was, and I know you y'all feel that you've sort of answered this to some degree but would appreciate you circling back a little bit and then trying to be as specific as you can as to what constitutes failure or success of a stent. What are the factors that make you think, wow, this worked great, or it did not?

Dr. Pradeep Ramulu
It did not. I think this is somewhat independent.

Dr. Elyse McGlumphy
But I think this is somewhat individualized. Sorry, is someone else talking? So, I think this is somewhat individualized to the patient, uh, it sort of depends on the goals of why the physician placed the stent to begin with. And I think the main goal for all of us in broad terms is we want to achieve success and that's an intervention which improves the patients quality of life and prevents their vision. And that's our main goal. But it's really individualized whether one person needs to get off medication because they have intolerances, whether another person is just not adherent, whether they're losing visual field despite our treatments. I think that the indications that we choose these things are different for everyone, but I think the success is defined by preventing them from losing their vision and improving their quality of life.

Dr. Pradeep Ramulu
I think there's some objective things that we can say are failures. If somebody had a stent related complication that caused inflammation or things of that nature, if somebody needed another pressure to lower another surgery to lower the eye pressure. I mean these are objective things that I think you can say our failures of a stent. So, there's some things that are individualized. I agree. But then there's some things that I think are purely objective.

Dr. Geoff Emerick
Right. Agree with that and as far as a success would be to maintain and hopefully decrease the need for medications. Just to emphasize, this so important for our patients they're expensive, they don't remember to take them, they can't take them, they're physically unable to, you know, a lot of our patients are elderly. So again, difficulty remembering, they don't have family members to put their drops in. So, to be able to decrease the medication burden is just a huge quality of life. Is it meaningful and also just in terms of treatment of their glaucoma adherence to medications is such a big problem. I mean, even in the best conducted studies, about half of patients took fewer than 75 percent of their

prescribed drops. And so, we might think that their drops are working because they took them right before they come into our office. But that may not be what's happening.

Dr. Michael Repka
I was going to add that one thing that some people might be tempted to use is progression on the visual field. And although it would be nice to not see the visual field progress, I mean, some patients are going to continue to progress in spite of the world's best treatment, perhaps because we don't know all the factors. But I wouldn't want somebody progressing on visual field necessarily to be considered a failure.

Dr. Geoff Emerick
Right. So, it's slowing of the visual field progression.

Dr. Michael Repka
Yeah.

Dr. David Glasser
And they may be progressing more slowly.

Dr. Lisa Banker
So, is there any alternative to stents for open angle glaucoma. Obviously, I'm sure there is, but would like to have you guys embellish on that. What you consider to be the current standard of care and where stents fit into that armamentarium.

Dr. Geoff Emerick
In addition to medication as invasive as selective laser trabeculoplasty SLT. We typically offer that to patients with open angle glaucoma. We think that will help to lower their IOP. The potentially decreased their medication burden so that would be the least invasive and then in order of increasing invasiveness, there's viscocanalostomy. There are goniotomy all the ways that we can do that whether it's trabectome, there's excimer laser and development for that cohort dual blade. All the different ways of performing goniotomy. There's a subconjunctival implants. There's turbulently surgery. There's two shot surgery and there's ciliary body ablation procedures. So, kind of it that in order of invasiveness.

Dr. Lisa Banker
And so, with all those things you mentioned how is it decided? Is it just kind of a provider preference? You know, what they're comfortable with, what they know about is what guides you one way or another?

Dr. David Glasser
I'm going to say the shorter answer is three years of residency and a year or two of glaucoma fellowship, but I'll let the guys who actually do this expand a little bit more.

Dr. David Sola-DelValle
Yeah. I mean, there's so much that goes into that decision making. I mean, it depends on the patient's socioeconomic factors, what worked in the other eye, are they on blood thinners? How elderly they are, how young they are. I mean, there's so many things that go into that decision making process and we've been talking about it in the, you know, each patient needs something different. I would actually go further and say each eye needs something different. I've had patients who have ocular hypertension in one eye and severed in the other and offer completely different treatments for each eye. So, it has to be

very, very visualized. As David Glasser said, it does take three years of residency and one to two years of Buckman fellowship training to really be able to make the decision. Also stay on top of all the literature that's coming out every year on all these devices and new procedures.

Dr. David Glasser
And you know, it wouldn't be surprising to get three different answers from two different glaucoma specialists. And I don't think that's unique to Glaucoma or Ophthalmology. Any field in which there are multiple approaches, therapeutic approaches to treatment of a disease. You will have physicians who are more comfortable with A versus B either because of personal experience or because we're they trained that's what they did. So, you know, it's just not something that can be reduced to a flow chart, I don't think.

Dr. Lisa Banker
OK. And so, we talked a little bit tonight about how the actual evidence out there to compare long-term outcomes of, say, a standalone stent versus a combined cataract and stent versus just cataract alone. I think we all sort of agree that evidence is sort of nonexistent there. The evidence hasn't been built in that way. And if I'm wrong, by all means lean in and tell me that. But I guess I wonder with that fact perhaps out there, what do you all think about the newest stent indication which again is the infinite stent situation with the three stents having the FDA indication of glaucoma really being uncontrolled by prior medicines and surgery? What do you think about holding to that sort of FDA indication which is in place for that stent system?

Dr. Geoff Emerick
I think we would consider certainly SLT to be a type of glaucoma surgery so that that would fit in that indication. So, what I mentioned before about refractory IOP is not adequately controlled on tolerated medications. And then if prior incisional surgery has been done or prior laser surgery has been done that that would fall under that indication.

Dr. Lisa Banker
Is it your experience that most of these patients have undergone laser procedures in the past?

Dr. Geoff Emerick
The majority.

Dr. Lisa Banker
How good do you think your colleagues, your general practicing colleagues, are at documenting those circumstances about their patients?

Dr. Geoff Emerick
They're really good. And I think your patients and physicians consider SLT be a, you know, significant at surgical intervention and records that I get usually have that pretty well, very well documented.

Dr. Michael Repka
I think that we know there are many instances of where record keeping may not meet a future standard. But I think we've also shown that our members can be taught how to document properly when necessary and certainly you all have seen that with cataract surgery where it does take people updating what they've been doing with each LCD iteration and they can learn to do it, although not quite as quickly as the day of publication on those documents.

Dr. Lisa Banker
Think we're still working on that, doctor. I don't think the LCD's have changed for several years on that.

Dr. Michael Repka
Well, well, yeah. But you all have somewhat. You do have some differences and changes and it is an ongoing educational job, which we do seriously take on and will continue to.

Dr. Karen Allison
So, the problem with glaucoma is that there is no cure. So, these are all treatments, and these treatments may last a year or two years. So, we're always trying to find something that will work specifically for each patient. So, the fact that they may have a cataract surgery and iStent® or whatever spent that, but we choose and after two years they may need another procedure does not mean that the procedure failed. It just means that there is actually no treatment that's curable that the patient will never have another procedure. Cataract surgery can lower the pressure by two to three percent depending on the type of local OMA. As Dr. Glasser said earlier because a lot of patients cannot afford the medication, they have side effects from the medications, they are unable to put the medications in, and so that's an option and the standalone procedures will also help patients that probably had cataract surgery before and may need another procedure instead of having a more invasive procedure, they could have a similar set procedure that will work for them. So, these are all things that we have to look at and also knowing that in another 20 years the amount of patients that are going to be diagnosed with glaucoma is going to be in. It's instrumental in US finding a way to treat these patients that they won't progress to blindness. The whole issue is to prevent patients from going blind. So, it may seem as if there's a lot of different treatments out there, but they all work, and each physician has to find what works best for them and what works best for each patient to prevent their disease from progressing.

Dr. Lisa Banker
How does it play into the scenario for all the patients, you know, since glaucoma, as far as I understand it, the pathology is really still poorly understood. You know, despite over 100 years of dealing with this on stage. What about the patients who seem to have decently controlled IOP and yet still lose vision and go blind? What's your commentary on that? I mean, in other words, how do we know, you know? And you're chasing the IOP and you're controlling the IOP and yet they still I guess that's my question, are we chasing IOP and not really impacting the underlying etiology of glaucoma?

Dr. Emily Jones
I think you're asking a really good question. I think we all know that glaucoma is not simply defined by pressure, but we also have decades of good studies that show that controlling the pressure across the population, you know, not in every single patient but across the population, controlling the pressure will slow the progression of the glaucoma. There are a handful of patients and happily, it's not the majority who seem to have a very pressure independent form of glaucoma. And there's a population of patients who have fast progressing well. So, we do a couple of things for those patients, and this is a little bit off the topic of MIGS cause a lot of these patients again, it's a small group, but a lot of these patients are not ideal MIGS patients. And we when we first inherit a patient, we often order a few visual field tests in rapid progression to make sure we're not seeing someone who's a fast progressor. Also, if we see patients who have excellent low pressure and are progressing with their glaucoma, there's a couple of things that we do. We make sure that it is actually glaucoma. Often, we'll do a CT of the brain and make sure that they don't have something that looks like glaucoma but is actually a compressive lesion or

something in there, you know, in their brain. And we'll also ask them about other factors like uncontrolled sleep apnea, systemic hypotension. There's some evidence that suggests that patients, especially, who have naturally low blood pressure or who are overtreated with their blood pressure, may be dropping their blood pressure overnight and failing to perfuse their optic nerves. And honestly, I hope that I will live to see the day when we figure out what, besides the pressure is affecting glaucoma. But we just know that there's a lot we don't know. But again, happily, the vast majority of patients are protected by lowering their pressure.

Dr. Lisa Banker
OK. Thanks, Dr. Jones.

Dr. Pradeep Ramulu
I also wouldn't say that we don't know what those other things are. You know, I think people and humans and extensive work with animals have shown that mitochondrial dysfunction, glial dysfunction, you know, the Perry populator is sclera. And the stress placed and the fibers as they leave the eye, you know, multiple other things that are known to be effective. The problem is that, you know, you there's no treatment for them and you can't detect which of those as contributing in an individual person.

Dr. Lisa Banker
OK.

Dr. Emily Jones
Agreed, agreed. And there are also suggestions like the differential between intracranial pressure and the optic. You know, intraocular pressure. There are things out there. Absolutely. But things that we can't really measure in a lot of cases or control.

Dr. Lisa Banker
I got you.

Dr. Pradeep Ramulu
That's not individually diagnosable, and independent of that, you know, the pressure still matters even in those people.

Dr. Lisa Banker
OK. So, question 7, we already talked about cataract extraction alone. So, the last question up here that I would ask is if standalone stent surgery is reasonable and necessary, are all the stents considered equivalent? And I know we touched earlier on the Compare Trial. It seemed to suggest buy in with any specific stent over another one, but it seemed to suggest that the iStent® underperformed the Hydrus in that particular trial. And so, I guess I just throw that out there as how do you all know, if that's the case, if evidence is starting to indicate that one particular device seems to be working a bit better? How come we're still OK with all sorts of stents? You know what I mean?

Dr. Geoff Emerick
I would say that Compare study compared the Hydrus versus two iStents®. There's good evidence that three stents are probably more effective than two, and that's what's done with the with the iStent® infinite. So, we don't have direct comparison between what is currently available or the new FDA approved stent with the Hydrus. I think we can say they are all very effective and again, we don't have that specific data on three iStents versus a Hydrus.

Dr. Lisa Banker
And I think that's important for us as payers. Something I really struggle with is, are you all just kind of relying on the CAT study? I mean, help give me some direction about what the best evidence is to suggest two stents is better than one stent, three stents is better than two stents. Does it end? And you can keep driving down IOP, but what is the evidence that shows that an IOP driven all the way down to 10 is so much better than 15? I hope you understand what I'm driving at, but how do we draw the line between the number of stents being stuck in at one time? It is there any value to putting in one and then waiting and seeing how things go and then adding an additional stent kind of going one at a time. Is there any value in that? Lots of questions there.

Dr. Pradeep Ramulu
Well, I mean, I would just make the general comment then when you're doing standalone surgery, you know, I don't think people take that decision lightly. And first of all, most patients won't let you do it. You know, if you're taking it lightly and you just say, oh, well, I'd rather just put it in the stent as opposed to starting you on drops. I think most patients will seek another opinion and not go forward with that. So, I think that the decision for standalone surgery is usually taken with a lot of seriousness. And I think the vast majority of our practicing Ophthalmologists comes to the point that if you're going to do it, you'd rather do it right with the least amount of risk. So, you know, I think that if you're going to do it, do you know you want to do it so that you don't have to go back and do something else? Understanding that you may have to, but you would rather put in all the stents that are reasonable at the same time that one time, so you don't have to go back and then do it again.

Dr. Lisa Banker
What supports the three stents is the right answer and the only reason I throw this out there is just thinking in cost effectiveness. I mean, I'm amazed at what these little, tiny titanium details cost. It's important, you know, throwing in three of them versus two of them. I think it's really important to healthcare cost effectiveness in the country and to people, taxpayers, you know, upholding the Medicare burden of that.

Dr. David Sola-DelValle
I mean I think it's a tough question to answer. I have a lot of thoughts about all the questions, so I'll try to put them together. But I mean one thing I'll say is I don't think there's good studies out there. Please correct me if I'm wrong. Comparing the cost of these tiny stents, which I agree is very high to using, let's say, latanoprost and combigan like three medications for years and years and years and many occasions are incredibly expensive as well. And I think I don't know, but at least for me when I add up all those years that my patients are being saved from using medications, it does become worthwhile between the Hydrus and the iStent®. I will say here in Massachusetts, a lot of my patients are incredibly educated. They go online, they Google Hydrus as I stand and they've told me I don't want to Hydrus, I want the little, tiny stent because it's less invasive. Yes, we have the evidence and the data, but we also have to take into account what the patients are telling us and what they want as well. And I don't think it would be fair for me to say, especially given that we do have some randomized clinical trial showing that the I stent is superior to like a pseudophakic or iStent® is superior to cataract surgery. For me to say sorry, I disagree with you. You have to take the headdress or nothing or just cataract surgery alone and then get stuck with the medication for another two to three years. So, it's a very complex situation. I don't think there's an easy answer to your questions Lisa.

Dr. Lisa Banker
OK, anyone else want to weigh in on that?

Dr. Geoff Emerick
Well, I think if you look physiologically, there is segmental flow through swims canal. So, treating more than just one spot is makes sense physiologically that that will impact more than one segment of outflow. And I think the CAT study showed there was incremental pressure lowering down to 14 or so with three stents. Once you get that low, that gets to closer to episcleral venous pressure. So, there is a limit to how low you can get with MIGS procedures to get extremely low pressures, you'd need really external filtration like a trabeculectomy or a tube shunt. So, I think we do have good evidence that three is better than one for sure. I think that for example the iStent® Infinite is packaged with three stents that can be placed by the surgeon in areas that will be most effective. That makes sense from a physiologic standpoint and there's no difference in cost if we just use one of those versus all three together.

Dr. Lisa Banker
OK let's proceed to just our last few questions now, switching gears a little bit into the goniotomy realm.

Number 1: for what types of glaucoma should goniotomy be offered as a therapy and sort of along with that, who is the optimal patient for a goniotomy? Is there someone in whom you should avoid?

Dr. David Sola-DelValle

Goniotomy, as you probably know, typically involves excising. That's a regular mesh worker. Removing that regular mesh work. So, I would say that any glaucoma in which there's a disease, trabecular meshwork, or decrease flow through the TM is a good candidate for goniotomy. And there's studies that have actually shown kanyama being useful not just in primary opponent glaucoma, but in sudo exfoliation, glaucoma and pigmentary glaucoma, congenital glaucoma, secondary glaucoma, steroid induced. In terms of what is an optimal ideal candidate, I usually think of, and I think this applies to make some general, but also to goniotomy as a patient with mild to moderate glaucoma where the angle can be visualized, and I can see the TM, or I can make it visualize. So sometimes I'll even take it. Someone who with who has angle closure, and I can still do the goniotomy when I can now fully visualized, the angle after I've removed the cataract and the ongoing scenic dialysis. I mean there's some people who, even with opaque corneas, could technically use an endoscope and visualize TM. But I think that's very uncommon and difficult. So, I think, again, an ideal patient is that mild moderate glaucoma patient where you can somehow visualize the TM and then people and who I would have avoided, you know, active or uncontrolled neovascular glaucoma patients or usually not good candidates for gauge dual blade. I think this is a soft thing, but someone who's done a lot of blood thinner. Sometimes I try to avoid it because you can get a big high FEMA on delayed healing, but it's I wouldn't count that as an absolute contraindication. Umm but yeah, I don't know. Is that good enough to answer the questions? Lisa, do you have any follow-ups?

Dr. Lisa Banker
So you're saying it would be at least at the time of cataract it would be best utilized in someone where you can visualize the TM, meaning that you can see synechiae or something obliterating that opening.

Dr. David Sola-DelValle
Well, where you can visualize the trabecular meshwork, or basically like scar tissue that can form but

you can actually break those during surgery. So, what I was trying to say is well, you can visualize the TM before surgery, or you can actually make yourself visualize that in the middle of surgery after doing cataract surgery using a gonioscopy lens and breaking the scar tissue to visualize the TM.

Dr. Lisa Banker
So perhaps a dumb question. How can you tell the TM's diseased?

Dr. David Sola-DelValle
Well, I think we assume on anyone where the pressure is elevated, I think we don't.

Dr. Lisa Banker
So we're going back to IOP again.

Dr. David Sola-DelValle
Yeah, we're going back to IOP again. But again I, as I was saying before earlier, I mean, I do think there's a lot of great data to show that decreasing IOP helps decrease glaucoma progression. So, I still think it is a valid endpoint and I do use it. So again, in someone who has elevated intraocular pressure and especially someone who has a glaucoma with nerve damage for me that person has a disease and if I can see it, it's OK to do it anatomy.

Dr. Michael Repka
I just want to add perspective here and that to remember that goniotomy is being questioned here in a sort of Medicare aged beneficiary. Of course, this is the number one go to procedure for pediatric glaucoma, so glaucoma specialists use this all the time, and it works for them with the mechanism that's been described which is simply opening the trabecular meshwork for better flow across that barrier. It works in kids, that scar that a lot of other surgeries don't work in.

Dr. Lisa Banker
Right. And so, some of us have discussed this in the past as far as what evidence is there to show that? You know a goniotomy should be done at the same time as a as another angle procedure or at the same time as a, you know, a cataract. You know just what strong evidence is there for that?

Dr. David Sola-DelValle
Well, I mean, I think it depends on what you define a strong evidence. Like my group actually put together a review that was published in 2021 for trabectome and it depends on how you define how you're doing the anatomy. But for Trabectome, there were six studies that were done between 2005 and three of them were perspective, three of them retrospective. They all showed they lower pressure, they lower medication for the caudal blade. There was at least nine studies I counted in 2022. There was even a recent study published by Brevetti looking at severe glaucoma patients, but there's like nine to 10 studies at least between 2018 and 2022 that have all shown that you can lower pressure and lower medication. You can come back and say that they're not randomized clinical trial, even the trials, even though some of them are perspective. But again, I think that's a really high bar to aspire to as we've discussed earlier in the evening. But I do think there is data and its peer reviewed data that has been published in journal. So, I think to say that there's no data is unfair.

Dr. Lisa Banker
OK. I'm going to temporarily step past the second question for a moment, but to kind of continue with the CPT® coding difficulty. But, you know, again the CPT® code that exists has classically been for a

pediatric procedure and it involves a lot of work and resources that perhaps you don't see in the adults and the Medicare beneficiary population. So, just kind of some of your thoughts about that difficulty and how some of these devices is truly performing a goniotomy. There are a lot of devices being publicized where they puncture it, sort of discrete locations and call that a goniotomy versus really requiring incision and excision of tissue that somewhat contiguous, you know, through a certain length of the trabecular meshwork to really count as a true goniotomy. So, I'm throwing out lots of concepts there and just want your free flowing thoughts about that issue.

Dr. Michael Repka
I'm going to start and say that Goniotomy does not have a definition in CPT® beyond what the practitioners have called whatever surgery they were doing. Obviously, it's simply meant an opening. So, it didn't even require an excision of tissue and most of the pediatric cases were not. I think it is fair to accept the premise that the goniotomy and a pediatric patient was an inpatient procedure, not so much anymore and did require a lot of post doctor visits and with the evaluation has been for the pediatric patient, I think that's all pretty much straight up, well known to you and in fact why the question comes up, what should we call these procedures in terms of the history? There is no amount of clock hours that was required. I think that we all recognize that you have to do more than nothing in more than some small amount. And of course, that's why we've at least suggested that more than 90 degrees or three clock hours as a floor on the procedure. But there's certainly no requirement based on the current descriptor for an amount of surgery, but I think we all would agree there's some part that you minimum and hence the proposal that we've made, though I would admit, is not, you know, sanctioned by CPT® other than CPT® Assistant has gone along with it for the moment.

Dr. Lisa Banker
Do you all have any thoughts about how many clock hours you'd look at for a goniotomy? Because again, I know you can say, well, there just shouldn't be any, but that's hard to write policy by.

Dr. Geoff Emerick
And all these procedures are accomplishing the physiologic purpose of removing the site of resistance to outflow, which is that trabecular meshwork. So, whether you're in sizing, exercising whether you're doing gonio punctures, if you're doing them over a sufficient area, you are accomplishing that seam purpose, which is lowering pressure by removing resistance to outflow...

Dr. Lisa Banker
What is sufficient area?

Dr. Geoff Emerick
Right.

Dr. Lisa Banker
I'm putting you on the spot. Come on.

Dr. Geoff Emerick
Right. Well, I think the three clock hours certainly makes sense physiologically. That's what's being treated with our currently available stents.

Dr. Lisa Banker
Now, how does a stent cover if you're putting in three stents? You know, putting one in and then

readjusting the angle on the instrument generally without even removing it and then putting in another one and putting in another one. My understanding is usually those three stents are within a 90 degree segment, but they're not continuously opening anything. They're just all they're discrete in and of themselves. And so, my question is how do you know trabecular meshwork is segmented to certain degrees? That's what many people believe the anatomy of it is. So how do you know that you're not just stuck in one segment out of the three that you put in and that you're really doing any good. To me, it seems that you'd have to have more of a contiguous procedure to really certainly say you're doing any sort of goniotomy. I struggle a little bit with the concept of putting in three stents means you've done a goniotomy.

Dr. Geoff Emerick
I believe there's about 30 collector channels, so you can be fairly confident if you're covering three clock hours, whether with stents or goniotomy that you're covering multiple collector channels.

Dr. Michael Repka
Yeah. So, my view is that this is getting access over 90 degrees or to those outflow areas and the crude goniotomy was the slice through the whole thing to get some of those canals. But you might be able to do that with just those three discrete entry points, but you're still accessing the 90 degrees of outflow because of those areas of the of the collector channels that you were in fact just talking about.

Dr. Lisa Banker
So in that scenario, why wouldn't you just proceed with the actual goniotomy, where you're sure that you've done the incision along the entire length, you're not just hoping and guessing that each individual stent is going to work so well. I'm just throwing things out there trying to understand. Not arguing. Just trying to understand. To me, if you'd wanted to be that sure, you would just do the goniotomy and not mess with three stents.

Dr. Geoff Emerick
There is a higher risk of high FEMA and the late high themas if you do that.

Dr. Lisa Banker
OK.

Dr. Geoff Emerick
So that's one reason.

Dr. Michael Repka
And it's possible the surgical openings could be occluded as well. I mean, they can scar back. So, it's not like it's a permanent slit forever in all cases. And in fact, maybe what you get are areas that are open in areas that are closed by the body.

Dr. David Sola-DelValle
Yeah, Geoff alluded to this already, but again with my patients, a lot of my patients can't come up. Blood thinners, for instance. And for me, that's very risky to do a dual blade or automate or trabeculectomy, some patients just want quick healing. I mean, they want to get off that one drop at night, but they want to see 20/20 the next day. And those patients, I do well for them, and I stent, or I will offer them iStent® Infinite because I will still be able to get some IOP lowering and decrease some medication, but they'll

be able to recover faster than with the goniotomy. The regulatory I think depends on the situation. Again, it's patient dependent.

Dr. Lisa Banker
Anyone else have anything to offer up? Any of the other Contractor Medical Directors. Any problems with proceeding with Goniotomy is in a bilateral fashion. That was the one other question we had on here.

Dr. David Sola-DelValle
Now I don't see any reason and I've actually done it myself several times. I think it depends on the patient. Again, I've had patients, for instance, who have some reason to do general anesthesia and if and they have elevated pressure in both eyes, so they're going under general anesthesia, I will do bilateral colonies even though they're adults and even older patients. So, I think it depends on the patient in the situation. But I don't see any reason why you couldn't do it bilaterally.

Dr. Michael Repka
My corruptible. Would you not expect David, that in fact that frequency would be totally opposite to the rate and the pediatric population? It should be really low or uncommon for other reasons as you suggest.

Dr. David Sola-Delvalle
Of course, yeah, I agree.

Dr. Lisa Banker
And then I think the last question was again, just garnering your opinions, but, you know, Medicare utilization data is showing a dramatic rise in goniotomy utilization. Standalone but particularly also in association with cataracts, with other angle procedures, etc. Any thoughts about that? That's sort of alarming when you see things increase, you know, hundred-fold over the course of several years.

Dr. Michael Repka
I'm going to comment on the utilization increase because these are big changes from very low initial denominators or low rates. So, the relatively small numbers going to drive a big number change. I'd also say that one thing in this space that has worked, I believe to the contractor has benefit and to the physicians is that when these when goniotomy does happen 75 percent of the time with cataract surgery, you're going to see a valuation of the combined service. And that process has been working as you've watched the confusion in our cataract family of codes develop and I would encourage that to continue because I don't see another way for you all to manage the situation frankly. So, I think those would be my two thoughts, one low denominator to start in Medicare so it's easy to show huge growth and it's still relatively small number of procedures.

Dr. David Sola-Delvalle
I mean, I would also add that it's easier to do or goniotomy and regulatory than it used to be. Correct me if I'm wrong. I feel like especially with the new blades, they're easy to use, they're easy to get. And I think that's also led to an increase in in use. So goniotomy, I mean, I myself, I'm a big fan of what I call C MIGS, combination MIGS. So, for instance, I do a lot of fake only speak on the otomy because I want to get again more app lowering and there's actually a study in 2021 that showed that code dual blade in addition to ECP and faco, it adds another couple points of IOP. Don't worry, you can get another

medication and decrease the medication burden for the patient. So, I think we're just realizing the power of mix and what can make can do for our patients instead of lowering pressure and decreasing medication burden. And we're realizing that it's relatively easy to learn and do so we're offering it more and more to our patients.

Dr. Lisa Banker
OK.

Dr. George Wandling
This is George Wandling. Can I speak?

Dr. Lisa Banker
I think we've gotten through our questions. Do any of the panel members have anything else to offer right now? Anything else they want to close with or mention?

Dr. Geoff Emerick
I would just add to the thoughts about the utilization increase is that the availability of these procedures has to the benefit of our patients has become available and used by comprehensive Ophthalmologists. So instead of just kind of throwing up their hands and well, all I can do is cataract surgery so that's all that I'm going to offer my patients. Then they're able to offer these other procedures which ultimately are benefiting their patients. They're not waiting until they're end stage of and sending them to us for their filtering surgery. They're able to intervene earlier, having higher success rates. And so that really in turn has led to the steady decline in traditional filtering surgeries, which did have higher morbidity and higher complication rates and required more post operative visits. So overall, our patients are benefiting from the expansion of these procedures.

Dr. Lisa Banker
Do any of the Contractor Medical Directors on the call have anything to add or ask?

Dr. George Wandling
Yeah. George Wandling here, do you hear me?

Dr. Lisa Banker
I'm sorry, Dr. Wandling. I was asking our Contractor Medical Directors. Tonight, we limited this to just the panel members and to our Contractor Medical Directors so I'm sorry.

OK, well, I've asked you all to stay here a long time tonight, but I hope this worked out for your schedules. Really appreciate what you guys do. Thank you so much for participating. We're very dependent on experts like you being willing to talk with us and answer questions, so just can't thank you enough for that, truly.

Dr. Michael Repka
Yeah. So, Dr. Banker, on behalf of the Ophthalmologists from both the Academy and AGS and others from the CAC that participated, listened, we thank you for the opportunity as well. We don't get the opportunity to do these often enough probably.

Dr. Pradeep Ramulu
Yes, thank you so much.

Dr. David Sola-DelValle
Thank you.

Dr. Lisa Banker
Yeah. Thank you very much guys. So, this will conclude the multi-jurisdictional MIGS expert panel meeting. And I wish you all a good evening and a terrific Happy New Year.

Dr. Michael Repka
Thank you. Thank you.

Dr. Karen Allison
Thank you. Bye bye.

Dr. Lisa Banker
Thank you. Goodnight.