SURGISIS ANAL FISTULA PLUG
COOK SURGICAL
Broadcast November 30, 2005

00:00:12.000
NARRATOR: Welcome to the Surgisis anal fistula plug discussion and procedure, presented live from Cook Surgical. The Surgisis anal fistula plug is a new paradigm in the treatment of anal fistulas, an innovative yet simple treatment for a notoriously difficult condition which has traditionally required surgical intervention. Your host, Dr. David Armstrong, program director of the Georgia Colon and Rectal Surgery Clinic in Atlanta, Georgia, will discuss the procedure and the device. You can send your questions to the OR at any time by clicking the MDirectAccess button on the screen.

00:00:47.000
DAVID ARMSTRONG, MD: Good afternoon and welcome to Atlanta, Georgia, for a live webcast about a new and innovative surgical procedure to treat anal rectal fistulas. The new procedure involves the use of a device called a Surgisis anal fistula plug. This is a biodegradable or bioremodelable plug which is inserted in a fistula tract, which then closes up the tract as the patientís own tissue grows into the plug and closes off the tract. As Iím sure many of you know, a fistula is an opening between the rectum and the outside skin, which forms as a result of an abscess. Fistulas are very, very common. Theyíve been known since antiquity. Theyíre also very painful, very problematic things for patients to deal with. They drain constantly. Theyíre very uncomfortable and once the patient has had one fistula, theyíre more than likely to develop subsequent fistulas, so itís important that we try and treat these fistulas as best we can and as early as we can. This new device is made of Surgisis, which is the same material weíre familiar with that we use in hernia repairs. Surgisis is a unique surgical material. Itís a biological material in that it is derived from the lining of the small bowel of pigs. This material is absorbed and remodeled into the patientís own tissue after itís been implanted into the surgical field. The new fistula plug uses this material and it is fashioned in the shape of a plug, which plugs the fistula, the same as we plug a hole or cork a bottle. The little plug is shaped not unlike a very small golf tee, in a tapering format. This plug is pulled onto the inside of the anal fistula, which is the high pressure end of the fistula tract, so having inserted the little plug in the high pressure end, it then becomes a mechanically stable configuration.

00:03:18.000
Weíll just go through a few slides on the background of fistulas as a little bit of background here. Fistulas have been known since the dawn of man and they have been treated for the last 2,000-3,000 years, as far as we know, by a procedure which is still performed today, called a surgical fistulotomy. What this involves is a narrow little probe is passed into the fistula tract, with the patient under anesthesia, and the tissue overlying the probe is then surgically divided or cut. Inevitably this causes problems with wound healing. Often there are problems with impaired control and inevitably the patients are in some quite significant discomfort afterwards. Another option is a device called a seton, which is a thread or a drain which is inserted through the fistula tract. It doesnít actually close it, but it does prevent recurrent abscess formation. Obviously the patient is reassured that theyíre probably not going to get another fistula, but they do have to deal with this persistent drainage. Another option is what is known as a core fistulectomy and closure. What this involves is excising or cutting out the fistula, which usually is about the same diameter as the inside of a ball point pen refill, usually 1-2 mm, but in a core fistulectomy, this tract is excised and then closed. The only problem with that is it inevitably makes the tract bigger before we try and make it smaller, so I personally donít usually use this procedure.

00:05:04.000
Another more recent procedure is whatís called an advancement flap. What an advancement flap is is a small flap of tissue which is created on the inside of the rectum and pulled down over the inside opening or the primary opening of the fistula tract, not unlike pulling down a shutter or pulling down a blind over a window. Of course,
we have to suture these flaps in place and there are sometimes problems with the flap retracting and there is a significant recurrence rate with this procedure. It also involves dividing muscle. It also involves a surgical procedure with inherent discomfort and usual potential complications. Finally, more recently, over the last 15 years, a substance known as fibrin glue, which is like a plasma glue, sometimes made from the patientís own serum, is made into a glue or a paste and then injected into the fistula tract in order to close up the tract. This was a sound concept and initially the results were very successful, but as the years have gone by, there has been a realization that the fibrin glue is not as successful as we had hoped because principally the substance is liquid and tends to run out, so failure rates as high as 85% have been reported.

00:06:29.000
In spite of doing these involved procedures, weíre still faced with fairly high recurrence rates. In some series, the recurrence rate is over 50%. Especially with fistulotomy, whereby the sphincter muscle is sometimes divided, thereís a significant incidence of anal rectal incontinence or leakage. This is over 1/3 in some series, over 30% in some series. All of these procedures, except fibrin glue, involve dividing tissue, potential anal-rectal incontinence, postoperative discomfort, and the task of trying to heal an incision. As the years have gone by, there has been some disillusionment with the fibrin glue procedure. More recently, authors have given to state their opinions in the titles of their publications, rather than in the text.

00:07:30.000
So, what do we do with a patient like this? A young, active male who has a job, has a family to feed, who has developed an anal rectal fistula, who has had multiple procedures, sometimes by multiple surgeons, who now can hardly walk, is in constant pain from constant draining fistula tracts and recurrent abscess formation. In this particular patient, there are at least 3-4 separate fistula tracts. Clearly this patient is not a candidate for a simple fistulotomy and the chances of fibrin glue being successful are somewhat slim. So, a new surgical procedure was devised, specifically to address these very complex anal rectal fistulas, which are much too deep to treat with conventional surgery, and in order to close up these tracts using the minimum amount of surgical invasion. The principle of closing a fistula, as weíll find out during the course of the next half hour or so, is to close the inside of the primary opening. This is the faucet which feeds the whole fistula tract. In the same way as you shut off your garden hose during the summer, you donít stick your finger in the end of the hose, you go to the faucet and switch off the faucet. So, for this reason, the first principle in closing these fistula tracts is to close the primary opening or close the inside opening. For that reason, we developed this Surgisis anal fistula plug. If you have a hole, you need a plug. The best material we have found for this purpose is Surgisis. It is a biological material, as weíve said. Itís remodeled into the patientís own tissue over the course of the following weeks or months, so thereís a very low risk of chronic infection, as seen with synthetic materials. There is no foreign body or allergic reaction. This is a sterile substance and all the antigenic material has been removed in the processing. It allows for tissue ingrowth. The substance is actually known as extracellular scaffold, which is a scaffold which allows the patientís own blood vessels to grow into the scaffold and then repopulate it with your own body tissue. In contrast to the fibrin glue, which is liquid and therefore obviously runs out, you can actually suture this plug, so you can actually stitch it in place so it doesnít leak out immediately after you’ve implanted the thing. Itís also an inherently simple procedure. As well see during the course of the afternoon here, the surgical principles are very simple, the technique is simple, but as usual, the devil is in the details and there are certain surgical steps itís important to follow to maximize the success rate.

00:10:43.000
Here is the Surgisis anal fistula plug. Itís rehydrated in water and becomes a soft and foamy consistency, which is easy to handle, sutures easily, and allows tissue ingrowth from the local tissues in the fistula tract. Weíre going to show a simple little animation at this stage on how to insert the Surgisis anal fistula plug. Here we have a patient laying face down, or in prone jackknife position, and we see the fistula tract entering the lower part of the rectum at the 12:00 position here. The most important first step is to identify the inside of the primary opening because this is what weíre going to close with the fistula plug. Here weíre using the surgical probes or hydrogen peroxide, which identifies the inside of the primary opening. Weíre pulling through a surgical thread or seton, to which the plug is attached. The plug is pulled into the inside. The excess is trimmed on both the inside and the outside. The plug is sutured in place. A very simple surgical procedure.

00:12:05.000
I just wanted to get into a little bit about the pre- and post-operative care at this stage because, as weíve said, the devil is in the details and itís very important to make sure that we follow all the minor steps that give us an
80-85% success rate, which we’ve been seeing in our group here in Atlanta. First, preoperative preparation. I think it is important to try to minimize the chances of infection of this plug by doing a bowel prep beforehand. This is a standard bowel prep that we do prior to a colonoscopy or a colon resection. Patients are used to doing it, very familiar with it. This is a standard procedure. Many of these mechanical bowel preparations include Colyte, Miralax. There are several on the market. What this does is just flushes out the system to decrease the amount of bacterial load in the colon. Enteric antibiotics, I think, help. This is also a standard step before we do colon resections. I personally use Metronidazole 2 gm the evening before. This is an enteric antibiotic which helps just finish up the job of sterilizing the bacteria in the colon. Thirdly, I personally use broad spectrum parenteral antibiotics at the time of surgery. Since we started doing this, we wanted to maximize the chances of the patient having a good outcome and to minimize the chances of infection. All of these steps are standard procedures that we use when doing a colectomy or some of these other complete anal rectal procedures.

As we’ve seen with the animation and as we’ll see in 2 films that we’ll show in a few minutes, the first and probably the most important step is to locate the internal or the primary opening. There are several ways of doing that. One is by using a little fistula probe and gently maneuvering it through the fistula tract until it emerges from the inside of the primary opening. This is sometimes the most difficult part of the whole procedure because many of these tracts don’t take straight shots from the inside to the outside. I personally find hydrogen peroxide very useful. This can be instilled through the outside opening, or injected through the outside opening, and it bubbles out through the inside opening, so you can see exactly where the primary opening is. At that stage, I like to put in a temporary seton or thread through the actual fistula tract. Every fistula is different and the anatomy is sometimes very variable, but if you use a 0 chromic suture, just to pass it through from the outside opening to the inside opening, then you know exactly where both openings are and you have a suture through the fistula tract. You can then use that suture to pull the plug into place once it comes time to close the primary opening. At that time, I give this tract another good irrigation with hydrogen peroxide. I think conventional surgical treatments or traditional surgical treatment has taught that the tract should be debrided aggressively using curettes. I think in many cases that’s maybe not the best thing to do because you want as narrow a tract, a mature a tract, and as fibrotic a tract as we can possibly have because that tract is going to be able to hold a suture and it is going to hold the plug a lot better than a tract which has been maybe curetted and the walls damaged and made less firm, so I do not aggressively debride the tract. It makes it bigger and that’s maybe not the best thing to do. I think the hydrogen peroxide not only mechanically debrides the tract, but also many of the bacteria in there are anaerobic and I think the presence of oxygen when the hydrogen peroxide bubbles out also acts as a bactericidal.

Then it’s time to pull in the plug. I personally either tie or stitch the little thread that we’ve already put into the tract to the plug. We’ve hydrated it 2 minutes in room temperature saline. You tie the suture or the thread that’s already in the tract to the plug and we pull it in. This is probably the second most important point to make. It’s important not to pull in the whole plug. The plugs are oversized, really just for ease of handling. It’s important not to pull the plug in too hard for 2 reasons. First, it compresses the vessels adjacent to the fistula tract and that will compromise neovascularization of the plug. Secondly, it will make more plug be present in the tract and therefore more material will need to be revascularized. So I think in this case less is more. If the plug is pulled in very lightly, as we’ll see in 2 of the videos coming up, it’s pulled in just snugly until you meet resistance. There’s a very obvious point when we start meeting resistance because there is an obvious drag on the plug. At this point it’s important to stop. Don’t pull in too much plug. Then, once we’ve pulled in the plug, on the inside we trim the excess, often 1î or even 1.5î in some of these smaller tracts. As you can see in this particular example, this is an anterior fistula in a male. You can see it’s a pretty deep fistula. I don’t think this would be a good case for a fistulotomy or any of these other procedures. Even though it’s a pretty deep fistula, you can see there’s still 1î+ of plug left exposed once we’ve met resistance, so don’t try and use the whole plug. Trim the excess plug, just so the plug is lightly in the tract. Here’s a second case here in a patient with Crohn’s disease. Again, this is a relatively short but deep tract, so in this case we didn’t need to use the seton. As you can see, we just pull the plug in with a pair of hemostats. Again, there’s 1î+ of the plug exposed on the inside of the tract. We don’t have to use the whole plug. We shouldn’t use the whole plug. This excess is trimmed, as we’ll see in some of these cases.
The next important point is to put a secure suture on the inside of the primary opening to secure the plug. The inside opening is the one which is subject to some reasonably high pressures, often as high as 80 mm Hg. Anybody that wants to put a blood pressure cuff on their arm and pump it up to 80 mm Hg, you'll see that that is a real pressure, so we need to put in a real stitch on the inside of the fistula tract in order to secure the plug in place. It is amazing that fibrin glue works at all, since it is liquid and had to resist these same pressures. What we use is a 0 Chromic or a 2-0 or even 0 Vicryl suture, but usually a 0 Chromic or a 2-0 Vicryl suture has enough mechanical strength in order to maintain the plug in place. I put my first throw in the head of the plug, having cut off the excess, for two reasons. Sometimes it is difficult to try and hit the plug when it is actually embedded in the tract because you can't see it, so if you put the first throw in the head of the plug when it is actually exposed in the surgical field, you can put this in under direct vision. So I put the first bite through the head of the plug, leave myself a tail to tie to later, and then pull the plug just deep to the internal opening and finish up the job by using the same suture to put in a figure of 8 stitch to close over the internal opening. I think it is important to close over the internal or primary opening over the plug. This accomplishes two things. First, it secures the head of the plug to the primary opening, which is a faucet, which is what we're trying to close. Second, it closes over the primary opening over the plug and protects it from the bowel contents, so it leads to a very mechanically stable situation. It is important that no plug be left exposed at the end of the procedure. We're trying to bury the plug. It has to be revascularized and obviously in order to revascularized, the local tissue has to be in direct contact with the plug, so it is important that none of the plug be visible at the end of the procedure. Finally, when it comes to the outside, or the secondary opening, I just cut the excess tail of the plug at skin level and then tack the tail of the plug to the edge of the secondary opening, taking care not to close up the secondary opening completely because this will create a closed space and this could potentially lead to a further abscess, so if you just tack the tip of the plug to the edge of the secondary opening and allow drainage, which there will be, and just leave part of the secondary opening patent in order to let the drainage occur.

00:21:51.000
Here is a schematic of all of that. It sounds a lot more complicated than it actually is, as you will see. So the first bite goes in the head of the plug. Put a couple of throws in. Pull the plug deep into the tract, just deep to the primary opening, then put your figure of 8 in, stitch up the plug, and you're done. As I said, it sounds a lot more difficult than it actually is.

00:22:17.000
I think we can move now to the first video that we have of this procedure and that will show us just how simple this whole procedure is. Here is a patient who has had multiple operations on an anal rectal fistula. The patient is under general anesthetic in prone jackknife position. He has a seton in place, a latex vessel loop which has been put in place after one of his prior surgeries. As you can see, there is an incision going radially from the outside of the secondary opening, going way distal out onto the gluteals, actually. Although now this tract appears somewhat short, it is, in fact, very deep. Certainly this patient is not a candidate for simply laying open the fistula because already we have impaired control as a result of all these procedures. Here we're flushing out the fistula tract with peroxide. As I said, I think it does more than mechanically debride the tract. I think it also has a bactericidal effect because of the anaerobic bacteria.

00:23:27.000
I leave the seton in place. Patients with setons are ideal candidates for replacing these because anal fistula plugs, the reason I leave the setons in place is these are your path finders. There is no point in taking the seton out and then trying to find your tract from scratch. We rehydrate the plug for 2 minutes in saline. As you can see, it is kind of like a wet noodle, almost. It has a soft, foamy consistency. It is easy to handle. You can place sutures securely through it. It will hold it. They don't pull out under normal pressure. Depending on the tract, I think it is useful to insert a tail on the plug, especially if it is a long tract. You can use this tail then to pull the plug in, as we saw on the animation. Here we're using a 0 Chromic. We're tying a 6î tail to the tip of the plug. We're going to cut the excess and there you've got a plug with a tail and you can use that to pull into pretty much any kind of tract you want to close. So now we're going back to the patient here. We're going to tie the tail of the plug to the seton and we're going to use the seton to actually pull the plug into place. There is no point in going back to take out the seton and try to find the tract from scratch. The seton has made the fistula tract as mature, as small, as narrow, and as firm as it possibly will be. As I said, these are ideal cases to close. So now we're going to cut the seton between the hemostat and where we tied the plug to the seton. Then you simply pull the plug in place. Obviously the thick end of the plug goes on the inside. It is like putting a cork in a bottle. The plug is pulled in
until you meet resistance. It is very obvious when you meet resistance. There is very little pressure applied, the same pressure as when you're putting a Foley catheter into a male urethra. It is very important not to pull the whole plug in, as this is really counterproductive. We trim the excess plug. As you can see, there is a good inch of plug left, which we excise and throw away. These are made oversized so they can fit pretty much any fistula and for ease of handling. Here we're going to put our first bite in the head of the plug under direct vision. You can see the plug. You know you get the bite in the head of the plug. It is a lot easier than trying to guess where the plug is when it is already buried within a fistula tract, so you put a throw or two, again using 0 Chromic in the head of the plug, and you pull the plug into place just deep to the internal opening. Then we're going to use our same stitch to put in a figure of 8 suture to close over the primary opening, using at least submucosa and preferably internal sphincter. These stitches, because we're dealing with real pressures here, these stitches go deep to the internal sphincter, not just mucosal, so we put a figure of 8 stitch deep to the internal sphincter, try and get a bite on the head of the plug, if you can hit it. We do a figure of 8 suture, so there is the first throw and here comes the second throw. Again, deep to the internal sphincter, try and get a bite on the head of the plug, if you can, and then you simply tie it off. Simple and mechanically very stable. It accomplishes two things. It keeps the head of the plug in the primary opening, so it can't be pushed out as easily. Second, it closes over the primary opening over the head of the plug, so it protects it from the bowel content. At the end of the day, you don't want to see any plug at either the inside opening or the outside opening, which we're going to do now. The tail of the plug, I usually just put my stitch in first, before I trim it, again using a 0 Chromic or even a 2-0 Vicryl, just a bite through the tail of the plug and tack it to the edge of the secondary opening. It doesn't need to be a deep stitch. If these plugs do fail and if the patient does do some excessive activity afterwards and the plugs do get forced out, 90% of the time they get forced out through the fistula tract, not backward through the rectum, so the key step is to suture the head of the plug in the primary opening. Stitching the tip of the plug to the secondary opening is belt and suspenders, but I think it is a prudent precaution, and then we trim. So at the end of the day, the plug needs to be buried into the fistula tract. You want to see little or none exposed. Then a little bit of local anesthetic is infiltrated in the region of the primary and the secondary openings. We've not divided any tissue. We've not divided any muscle. It is simple. The whole procedure just takes a few minutes and it leads to a very mechanically stable configuration. Over the course of the next few weeks and months, the plug is incorporated into the tissue by native tissue remodeling. After closing off the inside of the primary opening, the fistula tract dries up and there is no longer any risk, or minimal risk, of any recurrent abscess, drainage resolves, and it is a very effective procedure.

I think at this stage we have a couple of questions that have been emailed in. By all means, if you want to email question, either during this live webcast or afterwards, I believe the webcast will be archived and available very shortly. If you have questions that you'd like to email in, then the Cook people or myself will get back to you with an email response. The first one is from New York and it concerns leaving in the setons to let the tract mature. The question is should setons be used routinely after draining an abscess in order to insert a plug? I personally don't think it is mandatory, necessarily, to put a seton in every abscess that you drain, but I think it helps for 2 reasons. First, replacing the seton with a plug is a much technically simpler procedure to do than doing it without a seton for the simple fact, as we've just seen, that you can use the seton to pull the plug in place, so you're not struggling to find where the tract goes. I think that certainly applies with some of these complex fistula tracts with very long or multiple openings. The second reason is that once you have put a seton in, that will provide a tract which is as narrow, as mature, as fibrotic, and is the best setup to lead to successful fistula closure. Simply those mature fistula tracts are going to hold the plug and hold sutures a lot more effectively than one which is inflamed, with friable tissue and a lot of granulation tissue around. So I don't think it is essential, but certainly from what I'm hearing around the country and certainly our own data seems to be tending toward the fact that the results are possibly more effective with setons, although it is early days yet.

Here is a question, somebody put in a fistula plug about 3 weeks ago and there is still some drainage. This is a new procedure and with any new procedure there is a learning curve. We're all on the learning curve when we learn new things, but what I learned is once we've put these plugs in, patients often come back 2-3 weeks later and said they still had a little bit of drainage. At first, obviously, I was kind of disheartened, but after a while, it was obvious that this was part of the natural healing process. Once you've inserted these anal fistula plugs into a tract, I believe this drainage is possibly part of the resorption or remodeling process that goes on. This drainage
is almost the rule, rather than the exception. What I do is reassure the patient. I ask them still to take it easy. Sometimes, if the drainage goes on over 3 weeks, I'll add in a course of Metronidazole or Flagyl, either by mouth or topically, so just because we have some drainage after the anal fistula plug, we don't necessarily be concerned, especially in the first 2-3 weeks. I've had patients drain for many more weeks than that and still eventually close up, so as long as the fistula plug stays in the tract, as long as you stitch it adequately and as long as the patient takes care of it afterwards, then I think the chances of it closing by remodeling and by this tissue ingrowth are very, very good and it is important not to be discouraged because of some drainage. You've got to expect some drainage.

I think it would be a good time to review our experience to date here in Atlanta, first with a few patient examples. We have now been doing this for almost 2 years. We've been very encouraged by our results, not only with cryptoglandular fistulas, but also, somewhat surprisingly, with Crohn's disease. It is a very satisfying thing to be able to close a Crohn's fistula because, as you all know, that's sometimes not an easy thing to do. This patient had a hemi-horseshoe fistula with the primary opening at the 12:00 position. You can see we have two tracts, both secondary openings, obviously. It only takes 1 plug to close 1 opening. You can have 2 tracts, 3 tracts, 4 tracts, as many tracts as you want. If you have 1 opening, all the distal tracts should close up. The plug, in this instance, was pulled out from the more proximal secondary opening, where the whitish scar tissue is. This patient with a hemi-horseshoe fistula had a successful outcome with the first plug. Horseshoe fistulas are more difficult. Obviously horseshoe fistulas have 2 tracts, 1 primary opening and a tract going to the left and a track going to the right. I don't routinely put in 2 plugs. I choose the fistula which is the most accessible and the one which is going to be easiest to technically insert the plug. In this case, it was actually the tract on the left. If you manage to pull the plug through the fistula tract to close the common primary opening, assuming that both these tracts are fed by one common primary opening, then you should be able to close both left and right, in theory. In practice, our success rate has not been 100%. Our early success was only about 50% because the tract containing the plug will close routinely. The tract which was empty sometimes recurred, as I said, in about half the cases, probably because as this tissue was remodeled, the primary opening opened up enough so that the empty tract recurred. We're now more focused on closing the primary opening more adequately, using a bigger stitch, and our success rate closing 2 tracts with 1 plug has increased. Worst case scenario, if one tract closes, you go put a plug in the other side.

HIV/AIDS, there is no good operation for the patient who is significantly immunocompromised and has a deep transphincteric fistula. A lot of these patients need to have setons because a fistulotomy would take forever to heal, with very high risk of anal rectal incontinence, so again, this patient had HIV/AIDS with a fairly deep fistula, closed on the first plug.

This gentleman had a Delorme procedure as a child, 30 years ago, and had a draining fistula for 30 years+. We managed to find the primary opening adjacent to the anastomosis, which obviously was very distal. We gave it a good flush out with some peroxide, pulled in a plug, and this gentleman was closed with one plug, so obviously we were also very happy.

What do you do here? This is a young guy. He is in his years of maximum earning potential, wasn't able to go to work, obviously, because of this. Multiple operations. Obviously you can see a radial incision of the right gluteal region there. He's got 1, 2, 3, 4 setons in situ and it looks like 2 other tracts further up. Fortunately, we did a very careful exam under anesthesia with this patient. We put setons in this patient in order to mature these tracts, in order to make them as fibrotic, make them the most narrow, make them as mature as we possibly could and then went back 6-8 weeks later. Fortunately, he had one opening feeding all of these 4-5 tracts, so with one plug we were actually able to close all of these 4-5 openings, so obviously he was delighted and this is actually probably one of the more dramatic results we've had using this fistula plug. There was no real good alternative for this patient, so that was a very satisfying outcome.

Just to summarize, thus far, after doing this for the best part of 2 years, we have now enrolled 46 patients with high anal rectal fistulas. I think this would be a good point to emphasize this high anal rectal fistula concept because this is not really a procedure for a superficial intersphincteric fistula. The superficial fistulas,
intersphincteric and low transphincteric, can be treated very adequately simply by a fistulotomy. There is minimal risk of anal rectal incontinence. It is a very reliable procedure. The anal fistula plug comes into its own with these deep transphincteric and deeper fistulas. The deeper, the longer, the better for closing with this new fistula plug. So we have currently enrolled 46 patients and, happily, 38 of those fistulas have closed, which is a batting average of 83%.

Crohn's disease, as you all know, Crohn's anal rectal fistulas can be a very difficult problem to treat. We currently have enrolled 20 patients with Crohn's fistulas. These are very complex fistulas, often. 50% of our patients, fortunately, have just a single tract. Many, 7 of them, had multiple tracts, 2 rectovaginal fistulas, and 1 patient with multiple. I believe 5, J-pouch anal fistulas. The patient had a J-pouch at an outside institution and was found to have Crohn's disease. So of those 20 patients, we have successfully closed all fistulas in 16 of those 20 patients, which is a batting average of 80%, a statistic which is pretty satisfying.

I think at this stage we can go to the second video that we have. This patient is a young woman who came from out of state. Again, she had several procedures, I believe two fibrin glue procedures to try to close the fistula. The patient is under general anesthesia in prone jackknife position. A left lateral opening, obviously. Here we are, first thing, obviously, irrigate the tract, not only to identify the inside of the primary opening, which you can see very clearly here, but also to mechanically debride the tract, as well as, like I said, I think the hydrogen peroxide has some bactericidal properties. That is just my personal opinion. So here we are. We found the primary opening. So now we are trying to locate the primary opening so we can pull through the seton to pull in the thread. Here we have a fistula probe. This is a procedure that the Romans did. In fact, fistula probes were found in the ashes of Pompeii, so the fistula probe has changed little, if at all, in 2,000 years. Here is something which obviously is new. Here is a fistula plug, which is rehydrated for a couple of minutes in room temperature saline. You can see it has this foamy, floppy consistency. We're going to, again, put a stitch in the tail of the plug. This just makes the plug very versatile to use, especially if you've got a reasonably long tract, as in this patient. You don't really want to tie your thread to the plug and have it kind of come off halfway through the fistula tract. Then you're going to have to go back and start from scratch. So you may as well just take a few seconds to actually stitch a tail to the tip of the plug. That makes it a very versatile device. So here we are. We're going to tie the tail to the tip of the fistula probe. Again, we've not debrided this fistula tract. We want to keep this tract as narrow, as fibrotic, and as mature as we possibly can, so we don't want to go in there, scraping this and making this hole bigger than it already is. Here we're just going to put a loose throw on the fistula probe, tie it nice and tight, pull it through. It would be nice if these probes had a little eye on the end. So here we go. We've pulled the plug into the tract, pulling it until we meet resistance, which is there. Obviously when the resistance curve goes up sharply, that's telling you when this plug has got itself shouldered in the primary fistula opening, when it's snug. Just pull it in lightly or snugly. Do not try to pull in the whole plug. That is counterproductive. Here we are. We've cut off 3 cm, which is in excess of an inch, so don't try to use the whole plug. We're going to put our first throw in the head of the plug here. I believe we're using a 0 Chromic suture here. It's better doing this under direct vision, where you can actually see the head of the plug, rather than trying to put it blind in the fistula tract, when you can't really see where the thing is. So the first throw goes in the head. Put yourself a throw on. This is the Achilles heel, putting the stitch in the head of the plug. If you eliminate that potential drawback by putting the first stitch in the head of the plug, then you're off to the races. So then you pull the plug into its final position, ideally deep to the internal opening. Here it's protruding a little higher than I would ideally like it, but we're going to put our first throw through the internal sphincter here. We're going to force it into the tract with the actual suture and then go back out through the other side, again through the internal sphincter. This has to be a real stitch. These are real pressures that are generated down here. We're going to put a figure of 8 in. We're going to close over the primary opening, over the plug. The head of the plug is going to be secured into the primary opening. The primary opening is going to be secured over the plug. As I say, I think the explanation is far more complex than actually putting the thing in, but this makes a very stable configuration. At the end of the procedure, the plug has been covered over and is nonvisible. People have asked do you use endo anal flaps as well? I think that is overly complex and making an inherently simple, sweet little procedure into one which is just overly complex and adds in another list of potential complications. Here you can see the head of the plug has been completely buried over the primary opening. Now we're going to stitch or tack the tail of the plug to the edge of the secondary opening. Again, it's rare, in my experience, to see a plug migrate out through the...
inside. Most, if they're going to fail, which is usually because patients go swimming the day after, which has happened, or clean houses the day after, the plug is going to get forced out through the secondary opening, hence the importance of suturing the opening. So here we'll put our tail to the edge of the secondary opening. We're just going to put a little tacking suture there and we're going to leave the secondary opening open so we can have drainage. Drainage will happen as it remodels and there is inevitably some drainage as it closes up. This is not necessarily a mechanical closure of these fistulas. I think it's more of a kind of biological closure, as the remodeling occurs and it closes these fistula tracts with biological tissue.

00:47:40.000 We've got a few questions here. If the plug fails, is there any reason not to attempt a second plug? The ideal case for these plugs is these deep, complex tracts, for which there is really no good surgical alternative. I think the simple answer to your question is, if it fails, to look back and try to identify where it did fail. In my experience, we'll come to that a little later, in a couple of minutes, the principal cause for failure was the plug falling out. We address that early on using, instead of a 3-0 suture, now we'll use a 0 or 2-0 Vicryl. We tell patients to take it easy for 2 weeks. The failures have been from patients swimming the day afterwards, cleaning houses the day afterwards, and going for 8-mile walks on the beach in Hilton Head, all 3 which have happened. So I think it's important to try and identify why it did happen. If there is a fairly evident reason why it did happen, then certainly I would give it another shot and just address that specific reason.

00:49:04.000 There's a question here, are the plugs appropriate for a relatively superficial anterior fistula in a female patient? That's a tough one. Obviously anterior fistulas in female patients are the most prone for anal rectal incontinence by performing a fistulotomy, but superficial fistulas, especially intersphincteric, are really not ideal candidates for the plug because superficial or intersphincteric fistulas are easily treated with a simple surgical fistulotomy. I have had 2 failures when I tried this early on and the superficial fistula tracts I don't think have enough mechanical integrity or capability of holding the plug in place. The plug are held in place best by these deep fistula tracts that have a lot of tissue surrounding them that can keep them in place. So every case is unique and every case is different. I guess you have to just decide each case on its merits. Certainly an anterior fistula in a female patient would be an ideal candidate because that would eliminate any potential for anal rectal incontinence.

00:50:21.000 Are there any fistulas you wouldn't recommend trying to plug? We said already the very superficial ones. I don't think that's necessary. Horseshoe I think we've touched upon. Certainly those are ideal plug cases because the only alternative for a horseshoe is either a Hanley procedure or a modified Hanley procedure. I personally don't like doing those operations and I don't think the patients like me doing them either. So if you manage to close one tract at a time that's a horseshoe and you use two plugs, I don't think that is really an unsuccessful outcome. I think horseshoes are ideal candidates, especially with setons.

00:50:58.000 What's the role of postoperative antibiotics? Good question. I use topical Metronidazole afterwards, really because when we started doing this, many of these patients had already had a lot of procedures by a lot of surgeons and I wanted to make sure we had all the bases covered, the Is dotted and the Ts crossed. I can be accused of overkill, but I personally used topical Metronidazole 10%, which right now can be compounded in white paraffin or petrolatum, which is Vaseline to you and I. There's no side effects. There's no systemic absorption, or minimal systemic absorption, and I think it could potentially help out.

00:51:41.000 I think it's a good time now to move to some Dos and Don'ts. Again, this is a new procedure. We're all on a learning curve, but after doing this for 2 years, I think there are some points that are worth emphasizing. The first Do is do put a secure suture, either a 0 Chromic or a 2-0 Vicryl, in the head of the plug. Do make sure this stitch goes deep to the internal sphincter. This has to be a real stitch. These are real pressures that we're up against here. Do close the primary opening. I think it makes it a mechanically very stable configuration and minimizes the chances of plug extrusion. Do bury the plug. Obviously this plus gets revascularized, so we need to make sure that there is some local tissue for the blood vessels to go into, so it is important to bury the plug. Most important, tell the patient to take it easy for 2 weeks. This is 2 weeks of taking it easy that they're investing in the rest of their life. Most of the patients that have failed with plug extrusion are patients that just go out there...
and just push the envelope a little too much. They have minimal discomfort, which is good, but they really have to be told and encouraged to take it easy. They donít have to be bedridden for 2 weeks, but take it easy.

A few Donítts. I think it is important not to over-debride the tract. Here youîre making a very narrow, mature tract into one which is wider and probably just a little traumatized, so do not over-debride the tract. Thereís no point in making it bigger before you make it smaller. Another important point is donít leave the plug exposed. Obviously it needs to be revascularized. Leaving any plug exposed to bowel content or even the outside atmospheric air, itís not going to get revascularized. Most important, do not use too much plug. Less is more. Just put it in lightly, make sure, obviously, itís mechanically closing the internal opening. You donít want to leave it with any obvious wiggle room, but do not use the whole plug, especially in a long tract. With a very long fistula, even a 5 cm fistula, again, pull the plug in until you meet resistance and you can make yourself another secondary opening next to the anal verge. You donít have to use the secondary opening that the fistula made. You can make yourself another one right next to the anal verge and make it a lot easier to pull the plug in. The secondary opening will dry up once youíve closed off the faucet.

So, very quickly, just to finish up, a couple of complex fistulas, a couple of people have asked do you put a plug in immediately after youíve drained an abscess? The quick answer to that is no. Youíve got to drain the pus. Youíve got to let the tract mature. Youíve got to let this become as fibrotic as we possibly can and all this granulation tissue to resolve. Ideally, if you can place a seton, I think that technically makes insertion of the anal fistula plug a lot easier and will probably help the tract get mature a lot quicker. I personally use 10% Metronidazole to help mature the tract, especially with anal rectal Crohnís disease, because those are sometimes the most problematic fistulas to close. Then, once weíve had the chance to let this fistula mature, I go in and place an anal fistula plug, usually 6-8 weeks later. Thatís usually about as long as it necessarily takes. Finally, long tracts, there is an obvious temptation to pull the whole plug into a long tract. If youíve got a 4î tract, you obviously want to try to pull in a 3î plug, but as weíve just said, I think itís important just to pull the plug in lightly into the primary opening so you donít use too much plug. You can make yourself a secondary opening along the tract anywhere, closer to the anal verge, and use that to pull the plug in. Itís a natural instinct to want to pull the whole plug into a long tract, but again, you donít have to use the secondary opening the fistula made. You can make your own secondary opening and just pull the plug in lightly until you meet the first resistance, until the resistance curve goes up and the plug butts into the shoulder of the primary opening. Again, you edge it out, you trim the excess plug, put your first stitch through the head of the plug, snug it back into the fistula tract, put in your figure of 8, and weíre all set.

So, in conclusion, the Surgisis anal fistula plug is a new technology. Itís novel, itís simple, and itís a minimally invasive procedure with few drawbacks. It eliminates many of the problems that weíve been dealing with for the last decades, if not hundreds of years. The difference between fibrin glue and the anal fistula plug is you can actually suture the plug into the primary opening. This stuff does not leak out. Itís safe. There are no septic complications that we have encountered and it largely avoids the risks of anal rectal incontinence that are inherent in all these prior surgical procedures. I think, most importantly, itís effective. Weíre looking at 80-85% success rate in the deep, complex, cryptoglandular fistulas and, most gratifyingly, in Crohnís fistulas, for which there were simply no good surgical options available.

So I think that wraps up the webcast pretty much. Iíd like to thank you all for watching. Again, I hope you found this useful and informative in some way. This is archived and will be available very shortly, so you can go back and review it and pick up any points you may have missed. Again, Iíd like to thank you all for watching. We certainly appreciate your interest and your being interested in making life a little easier for these poor patients with these fistulas. On behalf of myself and Cook, Iíd like to thank you. Have a good evening.

NARRATOR: Thank you for watching the webcast discussion on the new Surgisis anal fistula plug. To make an appointment, make a referral, or request more information on the procedure, please click the buttons on the screen. For more information on the Surgisis anal fistula plug from Cook, please go to www.cooksurgical.com.