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Recently, Dr. Schwartz just published a paper in the Journal of Periodontology and she reviewed the literature from 1979 to 1996. It is an excellent review and I deliberately took this page so that you could not read it. I deliberately show you that to show you how incredible the number of research--this is animal as well as human reports. Now, some of the reports, the animal ones, are more standardized and general. Almost all of the human data is case reports.

So, I took out the human data so that you would not get bleary-eyed. I took out the human data longer than one year. And if you start to look at the number of implants, all different types of implants, different surfaces of implants, you start to look at anything from one-to-six year data and you start to realize that most of the data is up to six years, and there is actually quite a number of implants that have been placed in humans. Probably close to 600-some-odd, 648 implants if you want to look at the number exactly, seems to be about the number that has been out there and with an incredibly high success rate.

Now, this is a survival rate. This is not talking about bone loss or anything like that. But most of them are showing quite high levels of bone height radiographically

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but the survival rates, if you start looking at these numbers, this is the original Tubigen [ph] which has now been changed to the Frialit. But if you look at all the others, you will see that the high percentage of bone, I mean survival rate of these implants.

The only mistake on this was when I had this, this was Lange and not Branemark. I do not think that he--I am sorry for Klaus. I hope you extend my apologies to Klaus, those of you here from ITI. That was ITI. Klaus Lange at ITI. But look at the high percentage of success.

So, we know that this is at least comparable to delayed in most situations.

The Frialit work by Gomez was just reported. And what was interesting is that this is one of the few reports starting at least to look at one-to-five year data longitudinally. And what is of interest that they talk about immediate and delayed as well as very late, like nine month or greater. And that, I think, is one of the first studies that I have seen. If you look at just case reports, like the beautiful reports by David Gelb that is now updated up to almost, most of the cases that he showed in that original article, in 1993, are now over five years.

He still has over a 95 percent success rate. But he is grafting. He is doing all different types of things

at the top. He's an excellent surgeon and we see enough of this now to realize that this is a process that can work. So, if you look at the Gomez article, he compared a few different things, not just immediate placement, all right?

He had immediate implants. The failure rate was 1.16. The delayed was, that was within up to nine months, of seven days to nine months was .6. And the late or the re-ossification cases, meaning greater than nine months, typical of a perfectly healed ridge, was 3 percent.

So, you can see at least in the smaller population, this number was quite high. And even using the Kaplan-Meier statistical analysis, which this group certainly is familiar with and I think that's a high standard to hold yourself to, is a 96 percent overall success rate.

Clinically, just to show you a few things of where we are with this, when you have a smaller type defect with taking a root out and placing an implant in, what you are looking at especially when all the walls are there, you can do almost anything with this and it seems to clinically work. Becker has certainly shown this. But we still like to put a membrane on.

For small defects you might even use a resorbable membrane. This is open to discussion. For bigger defects,

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as you will see, we go with a membrane that is non-resorbable and that has some shape to it.

You can see here we just placed a demineralized, freeze-dried bone. We placed a membrane, a resorbable membrane on top and placed it over it. I hiked up the flap to get closure as you see here. And this case was done about five years ago. This is the immediate post-op. You can see how innocuous this was. This is only 10 days later. And here you see the ridge healed at six months and you can see that we have a very nice ridge and here is the final crown. And this crown, by the way, this is a three-year post-op.

So, we have an excellent ability to take and do immediate sockets. It certainly is something that can be done and can be done quite effectively.

When we start dealing with bigger defects like this, we have to start being concerned about how long the membrane is in place. I think we have to realize that the membrane should be in place for a minimum of four to six months and this is not just filling a defect with some material and closing it. Ideally this should be closed with a membrane. This one does not seem to close readily based on so many research, Lecombe, Becker and so on, in animals. We know that this is something which has to have a membrane.

Now, you can use different grafting materials. We now have gone more to mineralized freeze-dried bone, but certainly people have had great success with demineralized freeze-dried, as well as synthetic bone grafts. I will show you just two cases. This one was with mineralized bone graft material. You can see the bone graft placed.

I then placed a titanium reinforced membrane over the top of this, as you see here, closed. And if you see the before and after at six months, you can see that this now becomes a rather predictable outcome when you start to see the before and you start to see the after with the use of membranes and bone grafts.

Another case, it looks identical but it is different. You can see the large defects. When we have large defects with no buckle plate at all, we graft, and this one I grafted with HTR. You can place different materials under here. The key is the membrane. Put the membrane over the top and ideally it is otogenous based on Buser's work. But we also see the same success if the membrane stays in and is covered properly for six months, we see success with all of these graft materials. Here you see the membrane, I am taking it out. And here you see this similar kind of before and after kind of effects.

And here you see the before and after from the

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occlusive surface, not just height, but we also have width of the buckle plate restored. And this is today. You have all seen material like this.

This is rather routine and I just want to emphasize to the group, to the panel, that this is something that we can expect today rather routinely. That if you obliterate the socket, number one, you get bone deposition just like any other implant.

If you have a space then you can graft it. If you have a wider implant, as most of the companies have today, you can obliterate the space. If you obliterate the space it becomes basically just like any other implant when the bone is contacted. Because if you think about it, you really have, if you have direct bone contact you can have, it is almost, it is guided bone regeneration.

Because what you have done is you have blocked--it is really by contact inhibition--you have basically, instead of putting a membrane on top, you have direct contact of an implant to a socket, as you see in this case, like right here, in these cases of lower anteriors, if you get an implant to block out the complete extraction socket you basically cannot have fibrous tissue and epithelium going down here by contact inhibition. The bone stops it from growing down between it. So, you do not get fibrous

encapsulation.

I will show you this case lastly. This was a case in France, by a good colleague of mine, Dr. Tadeo, in Grenoble and he was kind enough to share this with me. He had taken these hopeless teeth out. He placed three implants. He then was going to look at this implant histologically six months later. He placed these implants in as you see here. He hiked up the flap in this case.

We are going to look at this implant. It happened to be immediately loaded also but that is not part of our discussion. I just wanted you to look at the histology of the bone so that you know when you obliterate the socket at the bottom this is the kind of bone integration six months later. This is human histology. So, this is not an animal. This is human histology verifying that you can get clear ossea-integration with remodeling and the haversian systems as you see here so beautifully documented in this particular case report.

So, do we know that this works? Yes. The key is histologically dealing with the top space. If you can obliterate the space at the top, it is just like any other delayed socket type of healing. If you do have a space, certainly greater than a millimeter, the question is just a matter of choosing which bone graft and which membrane do

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you want to use. But it is safe, it seems to be effective. And the 95 to 97 percent of most case reports that have been documented seem to hold this up at least on the one-to-five year data.

Some of them are approaching five to seven years now, and showing a similar high success rate. So, I think we are fairly safe in dealing with this.

I want to thank you for giving me the opportunity to present this to you.

DR. GENCO: Thank you very much, Dr. Tarnow.

Are there any comments or questions from the panel?

[No response.]

DR. GENCO: Thank you, Dennis.

We will now proceed to the next presentation by the Reimplants USA.

Oh, I'm sorry. John, did you have a question?

DR. BRUNSKI: Yes. Just a short question if I could ask Dr. Tarnow?

I think the panel is going to be faced with thinking about different kinds of implants and different kinds of indications. Do you have any comments on the immediate placement and the role of different implant configurations and designs and materials? Is there any choices to be made

there?

DR. TARNOW: I am presently doing research with eight different implants. So, I am familiar with utilization of most of the main systems today. I will tell you that when used properly they are all, at this point with early data, working very similarly in terms of their, their high success rate. I think the standardization of technique today is so well done and the machining and the parts and the drilling that I think that this, in the hands of any fairly experienced clinician, with moderate experience even, can handle this quite effectively.

We are seeing that long-term I do not have that kind of data. As you see most of this is case reports. So, longitudinal data greater than five years on immediate sockets is rather limited. Lazara's [ph] article in 1989, putting an implant, in this case it was a Branemark implant, putting a Branemark implant with Gortex over the top and submerging it for two months and then taking the Gortex out or at least placing it and taking the Gortex out at two months was the first use of a membrane, at least, with immediate socket placement.

This is in today's modern dentistry. The point that I am making here is that most of the implants seem to be successful. Most of the clinicians who have been using

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different systems, let us say only one system for years, John, have been doing it successfully or else they would have stopped. They would have stopped clinically. I think the key is how well it is done and also choice of case.

I think if you have pus coming out of an infected tooth and there is drainage and huge infections coming out, most people would agree that that is not a good selection of a case. But when you just have a fractured tooth or a non-separative lesion, these kind of lesions or some regular periodontitis or periodontal disease where the tooth is coming out, rather chronic inflammation, that kind of thing, this can be debrided very effectively and utilized.

We have also done it with acute infections with pus even coming out and still had success in many of these cases if you do full debridement, irrigation. But I think that pushes the limit again and is of higher risk.

But at this point, we do not see a difference yet clinically. Long-term with the integration we might have to look at that but that is five and 10 years down the road. But certainly it all seems to be working quite effectively now.

DR. GENCO: Any further comments or questions?

[No response.]

DR. GENCO: Thank you, Dennis.

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Okay. Next is the Reimplants USA, Inc., Mr. Phil Watkins.

MR. WATKINS: My name is Phil Watkins. I am part owner of Reimplants USA, Incorporated. We are in the midst of our 510 application and primarily why I am talking to you today is to show you an overview of our system. It is fairly unique and does not really fit the classification of the other systems that you have been evaluating, and, so, we would like to be included in your consideration for classifications as class II.

Reimplant is also an immediate extraction site implant. However, unlike the Friatec system this implant is a cad-cam milled duplicate copy of an extracted tooth. Essentially the application for this implant would be a situation where you have endo failure, a cracked tooth, limited periodontal concerns, advanced decay, something where you would be extracting a tooth but you would still have a respectful amount of cortical bone remaining.

It requires an a-traumatic extraction of the root and you have to be very careful not to fracture the cortical plate, obviously to maintain as much of that as you possibly can.

The surgical procedure rarely requires a flap. Generally you are just extracting the tooth and debriding

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the socket and reimplanting the implant. You will notice the little notch on the buckle of the tooth, that is to prevent confusion when the implant is placed back into the socket.

In addition, we take a small round burr and create a series of dimples to mark level of the alveolar bone immediately after extraction, like so. Then the tooth is replaced in the socket and using one of a series of different diameter probes the dimension of the space that has been occupied previously by the periodontal ligament is measured.

The coronal portion of the tooth is cut off at a 90 degree angle to the root and the remaining root is sent to the manufacturer to be made into a titanium implant. The canal space is enlarged so that a mounting jig can be placed into the tooth. The remaining root then is painted with a reflective lacquer so that the laser can read the surface of the extracted root.

It is then mounted onto a milling machine and the laser is activated. It reads approximately 80 points per revolution, four revolutions per millimeter. The computer then creates a schematic and at that point you have the ability to go in and adjust the dimensions of the implant to compensate for the periodontal ligament space so that you

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can enlarge the coronal portion of it to create more of a tight fit with the alveolar bone.

At that point the information is inputted to the milling machine and the milling machine creates the appropriate dimension implant out of this grade II titanium.

So, here it is as it is finished from the milling machine. You can see the faceted surface to give you increased surface area for better bone apposition. The surface is also grit-blasted to make it even a greater surface area with 500 micron alunus [ph] oxide.

At that point, the portion that will be coronal to the alveolar crest is finished down. And a crown margin is fabricated on which the restoration will sit. The coronal part is protected while the implant is cleaned to make it ready to ship it. You can also, if you choose to at this time, make a custom healing abutment for this implant since it is a one-stage surgery. However, that is not really necessary. If there is no flap procedure involved and there is no subsequent soft tissue damage, the propellate [?] maintains very well during integration.

This handle is attached to the implant. The implant is thoroughly cleaned. It is packaged in an autoclave pack and delivered to the dentist for implantation. The turn-around time is generally 72 hours,

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however, if infection is present you can go up to two weeks prior to implantation.

At this point the dentist after he has sterilized the implant will thoroughly debride the socket. Using a titanium forceps, take the implant to the mouth, it is tapped into position for primary stabilization and then allowed to integrate for the same period as conventional implants, six months in the maxilla, three months in the mandible.

As one-step surgery it does not require a membrane ordinarily and you do not have to close the site. The abutment system is very simplified. It is a series of preable posts that the doctor can place and prepare as he would a normal tooth preparation. At which point he will impress it and send it to the laboratory.

And here is the restored restoration. It is simple to do roots that have curvature to them. It is fairly, by the way you align the milling machine, it is not a problem. You can also do multi-rooted teeth. You have to block out in between the roots and create a fin there so that the laser can read the entire surface and then come back later and fit the implant to a matrix to get it back to the proper proportion.

They also have a ball attachment that you can

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utilize in situations like silver, you want to do a partial denture, for example.

In summary, I would like to say that I think thoroughly primary advantages of this, obviously, is that it is an extremely conservative procedure. And the alveolus and the surrounding soft tissue for the most part is unmodified.

As I said before, it rarely requires a flap. Very simplified restorative procedure, ideal emergence profile. As far as potential downside for the patient if the implant should fail it is generally due to a fibrous encapsulation that leaves the socket pretty much as it was before. At that point another implant can be placed or you may go to a conventional implant if you choose.

I think it is a system that finally is designed to fit the bone morphology rather than trying to make the bone fit the implant.

DR. GENCO: Thank you very much, Mr. Watkins.

Any comments or questions from the panel?

Yes, Leslie?

DR. HEFFEZ: Can you tell me what long-term, how many years you have been doing this?

DR. TARNOW: Yes. The technology was developed in Germany. They do have a three-year, multi-clinical study

that is showing a success rate of approximately 96 percent.

DR. HEFFEZ: How many years would you say?

DR. TARNOW: Three.

DR. STEPHENS: What is the cost of these implants relative to most other implants?

DR. TARNOW: We feel it could be comparable to an existing implant system, possibly a little less expensive but not very much.

DR. GENCO: So, for the panel's consideration, you are making the point that this could be grouped within one of the root-form types that there is no need to consider it any different?

DR. TARNOW: Exactly. It is not a coated implant, it is a grit-blasted surface.

DR. GENCO: Further comments, questions?

[No response.]

DR. GENCO: Okay. Thank you very much.

DR. TARNOW: You are welcome.

DR. GENCO: We will now proceed to Sargon Enterprises. Dr. Sargon Lazarof will make the presentation.

DR. LAZAROF: Good morning, ladies and gentlemen. I thank you for this opportunity. My name is Sargon Lazarof. I am the President of Sargon Enterprises and the developer of the Sargon Immediate Load Implant. I am a

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professor, clinical professor at the University of Southern California.

Last meeting you received a presentation from Dr. Hassan Nazari [ph], which was basically presenting the clinical aspects and the research aspects of it. I felt like there were some questions that were not properly answered because he did not have as long, as much knowledge on this implant. Since I am the developer I have the longest term clinical experience with this implant. So, I would like to address some of those questions.

Initially when I came here I was hoping that I would make an argument to include this implant as a root-form implant but judging from all the sparks that were flying earlier I do not know if I want to be in that category.

Essentially this implant is made of titanium alloy. It is an expandable screw implant. And basically all it does is it expands to custom-fit the prepared site. It eliminates that space between the implant and bone at times zero. And our research has shown that by eliminating that space between the implant and bone you can not only immediately load this implant but have better success at it.

This is basically a picture of the implant. As you can see, it is a screw implant and the top portion is

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the abutment. The implant can be expanded and we feel like this is the ultimate root-form implant because in anterior region of the jawbone where bone is harder it does not have to expand as much, so it acts as a single-rooted tooth. As you move posteriorly, it expands and acts as a up to five-rooted tooth.

It makes it possible for us to now perform this kind of treatment. I have done over 2,000 implants of this kind. Presently there is 5,000 implants that we have tracking of. And 15,000 implants have been sold but we have 5,000 implants that we have tracked because basically whoever we train has a requirement that they have to submit 10 cases after the initial course to get certified.

There is a three-year research at the University of Southern California which basically the initial one was a pilot study and then the second one is a prospective study which includes microbiology, immunology, and histology.

What we can do with this implant basically after extraction you can see the top left, if there is a pointer. At the top left portion you can see the tooth is extracted, the implant is placed and it is immediately provisionless. So the patient walks out of the office in this condition in full function.

There is no special diets or requirements that we

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give to the patient. This is the before. This is five years. This is five year clinical.

Now, what is very exciting about this implant is if you notice the top portion of this implant, the bone loss. Now, we talked about success criteria. One of the major concerns that we have with all present implants is the initial cratering that occurs. And our research shows that the reason crater occurs is not bacteria or perio-implantitis, it's basically implant design.

Any time you take a cylinder and put it under lateral forces, the lateral forces are concentrated at the crest. That is why the minute an abutment goes on a regular screw cylinder implant you get that initial crater and that initial crater is about a couple of millimeters added to the tissue depth. It is a periodontal pocket which there is always bacteria in.

So, if you go looking for bacteria in that pocket you will find it but we feel like it is a mechanical reason that causes that.

And just by reversing the mechanics of this implant and making the implant wider at the apex the entire mechanics of the system are changed and the lateral forces are transferred apically. So, we routinely do not see any crestal changes.

In some cases the ridge is really thin. You might surgically burn out the buckle lingual blade. You might see initial crater that occurs but we do not see progressive bone loss which I think this is more exciting than the immediate loading factor of it.

This is a posterior region. As you can see the implant reacts basically to the quality of bone. So, as an instrument it will tell us what type of bone we are dealing with. Depending on the amount of expansion, the amount of turns that you internally turn to expand it or radiographically we can site-type bone to either I, II, III or IV and the implant communicates to us to whether load it or not.

So, clearly, type I, type II and type III bones we immediately load and type IV, when the implant is fully expanded, is telling us there is hollow bone here, do not load it, so, we do not.

Also, the reason we hear about 100 percent success rates with this implant from university is very simple. The reason implants do not integrate is that micro-mobility that initially occurs and that happens in the initial two to three weeks.

Just because the implant is buried for four to six months that is when we find out when we uncover it. But

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that problem occurs in the initial two to three weeks. Now, we have a protocol that we followed this implant with. The initial two to three weeks are a very strict protocol that the patient has to come back once a week for a check. If there is any micro-movement present in the implant, if you percuss the implant you will see some sensitivity. And all you have to do to save this implant is to expand it further and restart the whole process.

So, we can save an ailing implant. If you place these implants and you never looked at them again, you loaded them and you never saw the patient, you would have about 70, 80 percent success rate. But we can increase that success rate by following the criteria and the protocol and save all those implants that are not being integrated.

Also, we have areas of type III bone, where it is basically a borderline between III and IV. If this micro-mobility occurs a second time, basically the bone is telling us, I cannot handle this load. So, we unload it. We expand it further, establish contact with bone. We unload it and we wait. So, our worst scenario is waiting for an implant to integrate.

This is what is exciting. As you have all seen the minute the implant is loaded, you get bone loss to the first threat. Now, the industry has accepted that. And

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patients have been going around accepting that. But what is exciting here is after seven years of loading--this is five years but we have a seven-year follow-up on this--we see bone growth past the collar, past the abutment joint which should be impossible. We do not know the answers why. We are doing research to find out.

Most of the research that is aimed--there are six research centers right now doing research on this. In April in Monte Carlo there will be a big news release and all these research centers will be releasing their data. They are focused not to find out whether this implant works or not because it clearly has shown itself to work; they want to find out why it works so well, why is it that we are getting bone growth through the margin of the crown and not bone loss?

So, it is true that we do not have 20, 30 year's experience with this implant. But if we have an implant that is in place for seven years and after seven years shows more bone or the same amount of bone it started with, there is a pretty good chance that the implant is going to be around.

We are not introducing any new chemicals, new surfaces or anything. It is basically a mechanical design that enables us to establish immediate contact with bone and

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maintain it. And that, after all, that is the whole ballgame, trying to integrate. The definition of integration is contact of bone to metal and we establish it as time zero.

Histological studies at the University of Indiana, again, formally they will be released in April. They clearly show that this is an osteon-integrated implant and we get osteon-integration both inside and outside the blade, increasing the surface area of osteon-integration to double the size of the same size of screw.

So, we can easily load this implant, a 10-millimeter implant, in the molar region with a molar, with a full force of a molar and it handles it much better. Again, here, this shows osteon-integration both outside and inside of the blades.

So, in conclusion, if this is an osteon-integrated implant, with the same materials and no new chemicals, we feel like it should be categorized as a root form implant.

Any questions?

DR. GENCO: Are you finished

MR. WATKINS: Yes.

DR. GENCO: Thank you very much.

You make the point that this should not be special retention? Why not?

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MR. WATKINS: The way we categorize implants, if I may suggest, at the University we look at implants at three categories. One, osteon-integrated; two, bio-integrate; three, fiber-integrated.

And osteon-integrated are implants that establish bone to metal contact directly. Now, whether they are grit-blasted or rough-end it does not matter. The bio-integrated implants have an intermediate layer which could be a HA coating, and then we have the fiber-integrated implants which basically can function with fibrous attachment.

Obviously a blade implant would fall under that. And then if you take a blade implant and make it a two-stage then it would fall into a category of osteon-integrated implant.

So, this implant basically all it is, it is a root form implant. Although it looks a little different it is a root form implant and it is a screw type expandable screw with the same material and I feel like it should be in the same category as the root forms.

DR. GENCO: Willie?

DR. STEPHENS: Can you tell me again what the success profile of this implant is?

DR. LAZAROF: My success rate because I am the

developer and I have had all kinds of experiences with this thing is lower than the clinical studies that are being done which are three year long at the University. My success rate, because I have tried placing it in the sinus, I have tried loading it immediately in type IV bone and I have failed, my success rate is somewhere around 85 percent with 2,000 implants.

But after developing the protocol and seeing that type IV bone cannot be loaded and you have the three week protocol and presenting it as such to the University, they have had us do, as you have heard from Dr. Nazari, they have had 100 percent success rate. And I know it sounds too good, but since the implant gives you a second opportunity for osteon-integration, even in case of failure you can save it, clearly that can be achieved.

DR. STEPHENS: Have you had any failures of the implant, itself, fractures in the body or--

DR. LAZAROF: Yeah. The implant is designed to expand within the memory of the metal, okay? So, when you collapse it, it can be fully collapsed. We have had a couple of cases that the blades were fractured but these, in placement of the implant you cannot tap bone with it. So, the surgeon assumed that the placement of this is similar to a screw type implant and did not tap the bone. So, he used

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the implant as the tap, so, tried to turn it and distorted the blades. So, he had to reverse it and replace, you know, place a new one.

But in function, we have never had an implant fracture.

DR. GENCO: Are there situations where you cannot use the implant? For example, if you had type IV bone and you had full expansion and it still was not tight, what would you do?

DR. LAZAROF: Okay. We feel like in type IV bone when it is fully expanded even in that situation where it is delayed loading it is much better to have a five-rooted implant trying to osteon-integrate than a single rooted implant.

But in the worst case scenario, let us say, the osteon-integration did not occur. If there is no attachment, the implant is fully reversible. You collapse it and you pull it out and the healing is exactly like an extraction socket, extracting a tooth.

DR. GENCO: So, those situations, let us say, mandibular posterior region where you may have type IV bone, hollow, if you fully expand it and it still is not firm, you would take it out and--

DR. LAZAROF: Oh, definitely. But we hardly--

DR. GENCO: So you would not use it in that situation?

DR. LAZAROF: No. But we hardly have cases like that because this implant can double in its diameter. So, 3.8 millimeter implant and once expanded it goes to 6.8. So, it does anchor.

In the previous scenario you had the screw that you were looking for some opposite side cortical bone to anchor it to, and basically even if you got osteon-integration, was basically on top and bottom of the implant, and after loading it you found out that it came out.

But this implant, by compacting the surrounding bone--now, we have plenty of data that shows--this is not pressure this is compaction of the surrounding bone just like in osteon-tone, [?], compaction of surrounding bone causes direct osteoblastic activity. And if you can see there is one other case that I showed. Routinely we see increased density around the implant after loading.

Now, we have--and the University of Renn [?] is definitely doing studies to find out what causes this increased density but we do see it clinically and they are going to show [?] slides showing it in April, why this occurs.

DR. GENCO: You have a narrow space, let us say, a maxillary lateral incisor. Is there any risk or have you had this happen where you actually would impose upon the adjacent tooth's ligament, the perineal ligament?

DR. LAZAROF: The implant never goes where the previous tooth was. If you see the anatomy of anterior teeth, the apex of the anterior teeth are always very close to the buckle plate. And if you followed up with the root preparation, [?], we always take a palatal angulation to these. So, we just move them two or three millimeters and take a palatal direction so the implant is always apical and palatal to the adjacent teeth.

So, even radiographically it might look like it is overlapping, it can never do that because it is weighted cup palatal.

DR. GENCO: Diane?

DR. REKO: Have you ever had a situation where you have expanded your implant and you have gotten osteon-integration around one of the wings that or the extensions that you have but not the others and subsequently had to remove the implant? I mean I can imagine.

DR. LAZAROF: Yes. If that happened, I would not be able to tell if it was osteon-integration around one blade or not. This could basically fall into a category of

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non-osteon-integration. If the osteon-integration was around one blade, obviously it would not handle the occlusal loads.

DR. REKO: But then you could not collapse it either to extract it either, could you?

DR. LAZAROF: Yeah. If there is no osteon-integration, you could collapse it.

DR. REKO: Right.

DR. LAZAROF: But if it is osteon-integrated the worst scenario is that in soft bone where the implant is wide expanded, let us say it is osteon-integrated and it is expanded and you want to remove it for some reason, which I have never had to, but if you wanted to remove it the defect from coring this out is a 7-millimeter defect, which is much smaller than the extraction of a molar bicuspid.

DR. REKO: But in the anterior portion 7 millimeters would be rather remarkable.

DR. LAZAROF: In the anterior region hardly ever you need that expansion because you can see it hardly expands because you have real dense bone.

DR. GENCO: Leslie?

DR. HEFFEZ: Just to follow-up on Dr. Reko's statement. Is it possible--you are assuming uniform expansion of that screw. If you achieve, if the expansion

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reaches a certain part of the bone which is already fairly compacted, that part of the screw will not permit the other portion to expand?

DR. LAZAROF: Correct. Correct.

DR. HEFFEZ: Just to finish the point completely, so, really what you end up doing is expanding the screw to where one surface of the implant is touching bone that no longer permits it to expand it any further?

DR. LAZAROF: Correct.

DR. HEFFEZ: It does not infer that the other surface is closer to the apposition.

DR. LAZAROF: Yeah. What happens in situations like that if one blade limits the entire implant expansion, the following week you find out that there is slight resorption and the following week you can expand the entire implant. Because that small contact on the implant was not enough to support the occlusal load. So, you will find that you can expand it further. That small load becomes like an orthodontic pressure and resorbs that area and then you can later expand it fully.

So, it has to have a full equilibrium in all surrounding implant for this to work.

DR. GENCO: Diane?

DR. REKO: Is it possible then that you could

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perforate the bone slowly?

DR. LAZAROF: Okay. Perforation of bone, if it is drilled, okay, if it is--

DR. REKO: No, no, not with the drilling. But as you are expanding your wings if you get some local resorption because of the pressure and then you do not think that you have it in solid enough and you expand it again, is it possible that you could come--

DR. LAZAROF: Not through the cortical bone. That would happen--like the instructions that we have it is full of very high pressure. It is not light pressure. So, if you are really close to the outside surface of the bone, possibly. But really to perf out through the cortical plate, that would be really difficult.

DR. REKO: No. I do not mean immediately with the pressure that you are doing it but--

DR. LAZAROF: Essentially? You know--

DR. REKO: --slowly because of the osteoblastic activity like in orthodontic appliances.

DR. LAZAROF: If you were to put light pressure at all times you would be able to do that. But the instructions are to go ahead and compact. The situation that the gentleman described as a hypothetical situation which basically I have not seen but the instructions are you

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go and compact one just like an osteon [?] would. So, there is a real compaction of the bone.

DR. GENCO: Further comments, questions?

[No response.]

DR. STEPHENS: One last question. How much of the threaded part of this implant is vented? How far does the splits, the wings, do they--

DR. LAZAROF: It is close to 50, half of the implant.

DR. GENCO: Okay. Further comments, questions?

[No response.]

DR. GENCO: Okay. Thank you very much.

DR. LAZAROF: Thank you.

DR. GENCO: We will now go to the Tronics Oral, Incorporated. And Dr. Raymond Schneider is going to make the presentation.

DR. SCHNEIDER: I will be working in combination with Barbara Ingalls. I am Dr. Raymond Schneider from Green Bay, Wisconsin, home of the Superbowl Champions again, hopefully.

What I am here to talk about is really that we, that the Board does not move implants, one-stage implants into, they maintain in a group, in group II. And I point out as an interest I am really not funded by Oral Tronics.

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It is Tronics Oral. It could be their future marketing in the United States will be to bring in an implant called the bi-cortical screw. It is a one-stage screw.

And I want to point out that it is site specific and that there is a risk in making limitations to the public for the public interest to, as a whole, not to restrict one-stage implants that would be under three millimeter, when they are under three millimeters if they would be considered class III.

Barbara?

MS. INGALLS: When you are reconsidering reclassifying to class II device, we are asking you not to make a restriction on the size of the one stage screw implant. The one-stage screw implant preceded the root form. Its design and protocol is most effective in the partially edentulous anterior arch and anterior fresh extraction site. The progress of dental health service to the public may be set back.

Our basic treatment options will be limited and doctors and the dental profession may not move forward in developing treatment for the partially edentulous patients and those needing transitional implant care. This will necessitate more grafting and enlarging surgical sites which will be detrimental to patients.

Doctor?

DR. SCHNEIDER: We are really talking about minimum treatment for maximum benefit and in that way the safety for the general public. I want to point out our basic tools that we know as a two-stage--

DR. GENCO: Excuse me, you have to be at the microphone.

DR. SCHNEIDER: I am pointing out here that we have basically two-stage implants and one-stage implants. And I am also pointing out there that we have a situation where we have a partially edentulous mouth and not a fully edentulous mouth. And what I am again looking at the design.

It is definitely in the design. It is not just surfaces we have been talking about much, it is also the length and the diameter of the implant in which I am referring to. There is a site-specific area and I would say we are not only talking about fresh extraction sites, we are talking about anterior versus posterior implants. Most of the implants that I saw today were put in the posterior unless they happened to be in a atrophic mandible.

There is a missing area, a missing link in the United States' treatment and that is that we are not designing implants that are narrow enough to treat the

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anterior portion of the mouth in a partially edentulous situation.

Barbara?

MS. INGALLS: The bi-cortical screw implant is a unibody, one-stage, non-coated, pure titanium, self-tapping dental implant. It is designed with apical load-bearing support in basal bone. Occlusal forces through the implant are directed to cortical anterior, inferior border of the mandible and the superior, cortical borders of the maxilla.

Therefore, it is a site-specific implant where length and bi-cortical support can be achieved in the anterior region.

The uni-body design is a one-stage surgery and a one-piece ready for prosthetic placement. This allows no micro-gaps for microbial contamination, no loosening of screws, smaller crestal width protecting bone in narrow proximal areas.

Site-specific indications for forces and anatomy of anterior narrow edentulous sites where cortical, apical or basal bone can be reached with long, narrow osteotomies and not endanger nerves or sinuses.

It was developed for edentulous ridges and fresh extraction sites of narrow anterior, single-rooted teeth. The osteotomy, fixation and load-bearing surface occurs

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below the apex, so leaving the delicate crestal bone and blood supply minimally traumatized.

Bi-cortical support is deemed gained below the crest. Success is not dependent upon grafting or primary closure. Only that the transfer of the post-operative load can be controlled through splitting on functioning natural teeth. This will permit healing of sockets with neighboring bone or teeth in the narrow anterior regions.

The problem is anterior and posterior teeth and bone anatomy differ. Posterior teeth are wider, mesial and distally. Anteriors are 5 millimeter average. Posteriors average 8.5 millimeters. This dimension critically decreases for anteriors lingually and apically but basically there is no change for the linear plane of posteriors.

This is not critical for over-dentures or multiple edentulous sites when teeth are not replaced one for one, however, in single tooth replacement, it is critical.

Doctor?

DR. SCHNEIDER: What we are seeing here is that the anterior portion of the mouth, as we know, is on a curve. Therefore, you have the anterior portion, there is greater width than there is on the lingual portion. Dr. Medford points out that when we place an implant in this area that we need approximately two millimeters on either

side so that we do not jeopardize the adjacent teeth.

This is not a consideration when you have an edentulous mandible maxilla because we are not confined to the restrictions that are opposed by teeth on either side.

When we are looking at this situation it is different. On the lower mandible, which Dr. Medford points out in the recent Journal of the American Dental Association, that he was pointing out in the article, "Single Tooth Implants," that rarely are implants placed in the lower mandible. The interesting thing is most implants are placed in the lower mandible but not in a partially edentulous situation.

The reason, he points out in this article, is because there is not adequate mesial and distal link that you are damaging the adjacent teeth. In a situation where you have a two-stage and a need for a two-stage implant, that in its design is required to have a wider diameter to encompass the component parts that rise above that point.

And in this design by having a uni-bodied design we are able to maintain strength and restrict that distance in not damaging adjacent teeth.

Other implants we are seeing as in Europe and this is where much of my training along with the International Congress of Implantology has come from, from Dr. Hans

Graffman in Bremen, Germany, where this implant has been and is designed. And its intention is to solve this particular problem of anterior extraction sites or anterior areas where we have narrow mesial distal component.

The difference in an anterior is that we have less force, we have longer bone, and basically narrow situations. So, the restriction on being narrower would restrict our possibilities of improving the industry of implant dentistry as it relates to single-tooth replacement.

MS. INGALLS: In the NIH of 1988, the National Institute of Health, consensus was the fewer teeth that are missing the more likely that an implant placement or failure could risk adjacent teeth due to the trauma to supporting tissues. The more teeth that are present in the arch the more the loads can be transferred to the natural teeth before and after treatment. This allows the design of the implant to be modified to protect adjacent teeth which is a different design than a root form or a plate form for edentulous arches.

Anterior single-tooth implant requirements are different than posterior. They are narrower and have more apical bone. The American public has shifted their attitude from implants replacing dreaded dentures to the attitude that implants are to be used to replace any missing tooth.

The public understanding and trust is this: If I lose a single tooth I can replace it with an implant. The teeth that are most important to them is, as they see it, their front teeth but the blade and the root form are not suitable for this area as they risk damaging the adjacent teeth.

DR. SCHNEIDER: Root forms basically and their smallest diameter now is near 3 millimeters. Where here the bi-cortical screw we are really looking at the trans-mucosal extension of a one-stage implant which would be, excuse me, which would be 2.25. But the strength of that we find there is clinically in my own experience of over 300 implants placed, that we do not have a fracture problem. We find that as the first, you know, the first interest, is it strong enough?

And the next issue is what is safe and effective? One of the things that we find safe and effective for a patient is when you are looking at a partially edentulous patient, for instance, a child, if we can eliminate in a congenitally missing tooth, if we can place an implant that does not have removable components to it, we reducing, which we now is the greatest problem is loosening of screws and parts.

I mean certainly a bridge, I think today there is

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very few implants on the market that I would recommend for my child that would be a two-piece because of their clinical complications with maintenance in the long-term. If we can eliminate those component parts then we can eliminate and make the implant safer and more effective. It is not always possible, of course, to remove those and in my clinical experience is that we do have certainly need for two-stage that is not my point. My point is that in a one-stage implant we can have a narrow transition and that we can maintain strength and safety and more effective implant.

At this time I did present to the panel some X-rays from a patient and I said this is typical. It was replacement of a single lower anterior tooth and at another time I will present all our statistics but at this time I wanted to ask the panel to not make a decision, that my thought was and I had heard that you would make implants that are under the three point diameter, the 3.3 millimeter diameter, that you would put that in a category of class III and I am asking that you not do that. That they maintain in a class II because of their safety and effectiveness.

Any questions from the panel?

DR. GENCO: We will go to Mark and then Willie.

DR. PATTERS: Dr. Tarnow was very concerned about the interrelationship between the implant and the coronal

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aspect of the socket in a one-stage direct implant into an extraction socket. You seem to have no concern whatsoever. What is the difference?

DR. SCHNEIDER: Okay. There, I am concerned about that area and what I am concerned about is I would want an area that I can treat just like a natural tooth. It cannot last forever. And the point I am trying to make is if we have to go and retreat that area I want an area that can be closed, it is this uni-body closed component in the trans-mucosal area. This implant gives me that and we find that really primary healing shown in other implant systems that if we can have a non-submerged implant the first healing around that collar is our best.

So, if we can achieve, when it is possible to achieve one-stage healing that is our best tissue component. Is that what you are referring to?

DR. PATTERS: Well, you have a 2.25 millimeter diameter implant going into a 5 millimeter diameter hole.

DR. SCHNEIDER: Yes.

DR. PATTERS: Therefore, you have minimally a millimeter all the way around the implant between the bone at the coronal aspect of the socket and the implant.

DR. SCHNEIDER: Yes.

DR. PATTERS: Dr. Tarnow thought that was of very

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serious concern and he was placing bone grafts and using membranes in order to get bone fill in that anything greater than one millimeter.

DR. SCHNEIDER: Yes. Well, our finding is that as long as it is disturbed, when you remove the inflammatory process in a single tooth, you are removing the inflammation that is caused by the bacteria, caused by the lack of--I am talking about we removed a tooth, put a fresh implant in that as you have seen in the panel, we have stopped that movement and the inflammation at the crestal bone. And without any grafting, without any additional procedures, that that crestal bone continually heals, that that defect is corrected because of you now no longer have that mobility component there that was in the natural tooth.

Does that answer your question? We do not have to graft and I am not saying that grafting is not necessary but in a situation where it was caused from the original defect, we removed the cause which was the ailing tooth and we replace it with an implant that we find that the bone regenerates to the height that is mesial and distal to the greatest height. It will resume its natural alveolar height.

DR. PATTERS: And it will bridge an area greater than a millimeter in your opinion?

DR. SCHNEIDER: Oh, it does, clinically there is evidence that it does. And it does in nature, too, if we would extract a tooth and leave it alone it would rise up to a certain level. Because it is scaffolded by the remaining bone on either side. So, on osteon-ostomy is now above the crest, it is all down below the crest and we allow it to heal up to the point of the undisturbed bone.

DR. PATTERS: Thank you.

DR. GENCO: Willie?

DR. STEPHENS: Yes. Can you tell me just three things. How long are the implants, one? Do they always go to the inferior border? And the third is, are you recommending that these implants be used in children?

DR. SCHNEIDER: Number one, do they always go. What you want to have is bi-cortical support. One of the principles of implant dentistry, not just compared, its trade name is bi-cortical. So, we are getting cortical support. And the reason for cortical support is because we want to anchor the apex because once again as one of the speakers noted that we are finding out if we have apical support, we have less crestal movement and, therefore, we are not losing that bone.

And because at the apex we have greater cortical bone. As Branemark pointed out that the quality of the bone

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was one of the main reasons his implants failed. Well, we are seeking out the highest quality of bone in that area.

So, to answer your point, what we want to do is go to the, we want to engage cortical plate. Sometimes, most often when you have a fully edentulous mandible you will see on radiograph that you are hitting the inferior border. When you have natural teeth you also hit the inferior but it would be more lingual too. So, on radiograph it does not appear like you are hitting the bottom but the protocol for osteon-ostomy is very narrow implants use very narrow drills. What happens we do not generate very much heat because of the smallness and we are bisecting the medullary plate. So, point is, yes, we intentionally in the protocol tap and sound the cortical plate on the other side to engage as best as possible bi-cortical support. That is why they are site-specific, they are meant for anterior to the sinus and anterior to the mentoferina [?].

DR. STEPHENS: On the mandible, how long are these implants?

DR. SCHNEIDER: That is a good question. They are 30 millimeters, the implants that are sold are 26 millimeters and 30 millimeters.

DR. STEPHENS: And you are recommending them for children?

DR. SCHNEIDER: Oh, when you say, child, I was talking about it cannot be a mixed intition [?]. Are we recommending them for children that have a fully developed intition? Yes. As is so is the National Institute of Health in that particular, where our guidelines are in the same instance. So, you have to define what the age of a child would be.

DR. GENCO: Further comments, questions?

[No response.]

DR. GENCO: Okay, thank you very much, Dr. Schneider.

DR. SCHNEIDER: Thank you.

DR. GENCO: We have next Dr. Gerald Marlin, who will make a presentation.

DR. MARLIN: I am Gerald Marlin. I am a practicing prosthodontist here in Washington and the President of Universal Implants Systems.

And as in the last panel meeting, I will be presenting as a manufacturer as well as a clinician. Universal produces a vediohex [?] implant restoration system which is an abutment that is designed to be used on a variety of different types of implants.

I appreciate the opportunity to present and address the issue of what constitutes appropriate regulation

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of abutments. I will present to you our clinical experience with abutments as they relate to their safety and effectiveness.

I will then address specifically question number three raised by the panel at the last meeting and will be amplifying on the remarks that I made at my presentation at the November panel meeting.

First, let me say that from the standpoint of a clinician I find that all of these implants work and they work very effectively, the coated and the uncoated. As we will discuss during this presentation, the problems are not of a manufacturing basis but they really are of a clinical nature.

We are comfortable with implants in 1998 and 1997 and before to such an extent that I had this patient here who was going abroad for three years and had a major concern that she was going to lose enough bone here during this period of time that she would be left without adequate bone to place implants, which would present a problem.

And, in fact, that the amount of bone that was being lost incrementally was gradually increasing. She was a patient of mine since 1976 and so, therefore, I had a very strong reason to believe that this would occur. And, in fact, you are looking at the panoramic film of the implants

having been placed and this is three years post-op. And you are looking at the fact that, in fact, that is what happened. Around the natural teeth she lost an extensive amount of bone, around the implants, the implants, in fact, maintained the integrity of bone as fully loaded with their abutments.

We tested the device by placing an implant at 30 degree angle and placing a 30 degree with a universal adapter for this particular implant connected to it. It is machine titanium alloy. And upon this, placed a custom cast post that was fabricated at a 30 degree angle correction, thereby, bringing it back to zero. And placing it within the Instra machine and cycling it through each specimen 5 million cycles apiece for a grand total of 20 million cycles.

What we are looking at here is that in spite of the 20 million cycles or the 5 million per, not one post bent or broke and not even one screw came loose. And this procedure was done many years ago before there were torque drivers.

What we're showing here is why abutments, not implants, are effective. And what we're talking about here is that this is not a mechanical problem. Problems that occur are really more of a clinical nature. These problems

of a clinical nature, with few exceptions, are the reasons that cause implants to fail, whether it's at the surgery or it's at the restoration. There are an awful lot of factors that are involved here, from case planning to the correct seating of an underlying abutment, to the method of temporization, how you go about it, the impression, how accurate it is, the occlusions, the angle corrections, emergence profile, the seating of the overcasting. There are a lot of responsibilities here for the clinicians to make it work. So we're talking about a lot of factors here that are, in fact, clinical that affect the prognosis and the safety and effectiveness.

In fact, when we look at a clinical X-ray and we look at the fact that this abutment is not seated, this abutment is not seated because there's any error in the machining of the abutment or the abutment/implant interface, it is a clinical problem. It is actually a manifestation of how good the osseointegration is because the bone fits so well that it started to go over the implant. And once the bone was contoured, now the abutment is now seated firmly in the patient.

What this slide shows is probably in one composite all the non-natural abutments that you can put in the human mouth. We're talking about an implant abutment. We're

talking about a custom cast post that is going into a natural root. And we're talking about a stainless steel endodontic post that is going into an endodontically treated tooth also.

Now, I will say from the standpoint of a clinician that I have far more comfort with an abutment sitting over this titanium root than I do with this gold post sitting in this natural root, which was obviously placed a while ago, and this stainless steel post that was placed in this root, again, obviously placed a long time ago. The reason why we know is because nobody is using silver points.

The problem that I'm having here is how do we classify abutments. Here we have a Class I device, this custom gold post and this stainless steel post, and yet I as a clinician have a much higher success rate with the implant abutment than I do with the gold abutment or the composite abutment.

As an example, just yesterday, from an anecdotal standpoint, I had a new patient in. We're in the middle of therapy, and, lo and behold, the custom gold post came out. Now in that particular instance, it wasn't the end of the world. All we did was re-cement the post. However, three months ago, I had a patient come in with a custom gold post in their endodontically treated tooth, and the tooth split.

And the patient had to have the tooth extracted and is going through six months' worth of orthodontics in order to either close the space or, alternatively, make a bridge because there was no room even for an implant because of the way the bone was fractured. Yet if it were an implant where the abutment fractured, then, in fact, we would be dealing with just replacement of the abutment.

So now from a personal perspective as a clinician, I would have to say that probably per year I have seen posts come out or roots fracture in maybe five different teeth over a ten-year span, and I've probably seen 50 of them. And yet since 1987 to 1997, I have only had to refix three implant abutments, and this is out of 720 implants. And yet those three abutments were actually manufactured before 1987 and placed before 1987, so I'm not even sure about the statistical analysis. Since 1987 to now, any abutment that we have placed has not had to be redone. But yet out of, say, 500 endodontically treated teeth, we've seen a higher number of replacement.

The service to the patient can be great, obviously. Before we had the osseointegrated implant, this patient, perhaps because there is a very long span here, would not have been amenable from here to here to something of a fixed nature. So we know that the integrated implant

is something that is quite beneficial to the patients.

If we could put the lights up, and we'll put the overhead on.

Turn the lights off. I'm sorry. Next?

Let's address Question 3 as posed by the panel, but somewhat modified on this handout. Number 1, should abutments be classified separately from the implant fixture? And what is needed to provide reasonable assurance of safety and effectiveness for abutments that are sold separately?

Next?

Should abutments be classified separately? Let's take the first part of that issue. The answer is an unqualified yes. And why do I say that? The long history of safe and effective use of abutments provides the strongest argument for their separate classification from the fixture. The abutment, even into the post and core abutment, but certainly for the implant abutment itself, there is a long history of safety and effectiveness, and we'll go into that.

As you saw at the slide presentation just now, the abutment is a stand-alone device. It's very comparable to an endodontically treated tooth with a post and core. And a separate classification of abutments still allows the FDA to provide the appropriate degree of regulation.

Next?

Should abutments be classified separately?

Presently abutments are regulated as accessories to implants. We all know that. That's why we're raising this issue. And unless the abutment is classified separately, that same abutment that is placed on a Class II implant would have radically different testing and regulatory requirements than if it were placed on a Class III implant. And keeping it as an accessory to a Class III implant would impose unnecessary and enormous financial burdens on small manufacturers, in addition to raise costs across the board.

Those who argue against a separate classification for abutments do so out of commercial interest rather than out of a concern for safety and effectiveness. Industry and clinical experience lends support to this statement.

Next?

Between 1987 and 1997, over 3 million implants have been placed and restored with abutments with success rates that we've heard all morning long between 90 and 95 percent in the hands of everyday clinicians. Now, we've even heard numbers higher than 90 to 95 percent, so being conservative, we're talking about that rate.

Abutment results have shown minimal clinical problems caused by design and manufacture. In our

experience, this is confirmed with what our experience is.

The MDRs show that most problems are due to clinical error, not mechanical design. And the materials in abutments that have been used safely and effectively over the last 14 years, we all know what they are. We all know what's acceptable.

Rigorous bench testing, which I showed you in the original slide, which we all know applies stresses that are much greater than those generated in the clinical environment. That alone determines whether an abutment has sufficient strength.

Even though abutment failures are rare, patient safety is not compromised because the repair of an abutment failure is not difficult. The repair is simply either replacement, screw tightening, or prosthesis rework, with, again, no damage to the underlying implant fixtures. Safe and effective for the patient.

This operator has not ever lost an implant due to a defective abutment, and this is out of 720 implants that I have restored. There are precedents for reclassifying accessories by the FDA.

Finally, as demonstrated in the slide presentation, abutments and implants in endodontically treated teeth are very comparable. They both support a

crown or other prosthesis. They both have a long history of safe and effective use. And they both are stand-alone devices from a clinical standpoint.

Now, let's examine this particular question because I'm quite troubled by the wording of the question. It says: What is needed to provide reasonable assurance of safety and effectiveness for abutments that are sold separately? I have a problem with that because we have the same product here. Regardless of who's fabricating the abutment, we have an abutment, and all abutments are the same product as far as safety and effectiveness. Why would we require a more rigorous testing process for one, especially given the safety and effectiveness that we know exists? And this discriminates against the small companies, giving advantage to the large ones, without any benefit whatsoever to the public.

In addition, manufacturers already use rigorous bench testing, accepted materials in fabricating their abutments. And as I have shown in the slide presentation, abutments are stand-alone devices like the post and core. They both support a crown or a prosthesis, and the post and core, as we know, are Class I devices.

What is needed to provide reasonable assurance of safety and effectiveness for abutments that are sold

separately? Coming back to this question and the question of specific controls, which is not on this slide but which was registered in the handout. What specific controls could we add that would be beneficial for implants as well as abutments? Perhaps independent standards organizations would be helpful in developing the appropriate testing criteria.

But more important--and probably this is the biggest key right here--is the allocation of resources for effective education programs, technique manuals, and teaching aids for instruction in the proper restoration techniques for implants. This is very important. This is probably more important than any other factor because of all the factors that I mentioned that are clinical factors that affect implants and abutments versus the machining of abutments.

Next?

We're at a crossroads here. We have an opportunity to protect public safety while at the same time minimizing excessive regulation that will absolutely stifle innovation and pull valuable resources away from educating the clinicians. There is really a lack of need for special controls except in the education area, where we are teaching the restorative dentist to do the job better.

The implant abutments themselves should be classified separately from implant fixtures. They are definitely stand-alone devices. And all implant abutments should be treated equally by whatever standard is applied, whether they are manufactured by Universal or they're manufactured by a manufacturer who's manufacturing an implant also. The standards are there, the specifications are there, in the plans and the drawings and the materials we use, and certainly the safety and effectiveness is there all across the board for abutments. So my conclusion is implant abutments should be classified as Class I or Class II devices due to their clearly demonstrated safety and effectiveness over a long period of time.

Thank you.

DR. GENCO: Thank you very much.

Comments, questions from the panel? Diane?

DR. REKOW: I'm not sure that I follow your logic that a small manufacturer of universal abutments is going to do a better job in educating the clinicians than the manufacturer of the implant who provides their own abutments.

DR. MARLIN: I didn't say that.

DR. REKOW: Okay. I'm sorry.

DR. MARLIN: I'm sorry if you misunderstood me.

What I was saying is that across the board, education is critical. And if you were to pull resources away to be put into testing that is like over-regulation, then how do we teach them?

DR. REKOW: I see. Can I ask one other question? If one company is making the abutment--I guess maybe I need to understand what you count as the abutment. Who owns the attachment and who worries about the mismatch, if any, between the materials types and any potential corrosion kinds of problems you could potentially have by mismatched materials in the oral environment? Whose problem is that?

DR. MARLIN: Okay. In the first place, the question of the mismatched materials I would say would definitely an abutment manufacturer's responsibility. I would take responsibility for that. I have restored both types of implants--I mean, implants both ways. I have used gold posts--out of the 720 implants, I can't give you an exact number, but about 350 were restored with gold posts directly to the implant, and I can tell you that the "galvanic reaction" that we hear about is so minimal that I have seen clinically that I'm not even sure that's as much of a factor--I'm not taking anything away from the couple of articles that were written about that, but does that determine that?

Now, I'm not personally threatened by that because we make machine titanium alloy connected to the implant with the gold post on it, and there's absolutely no way you get a galvanic reaction that far down. So I don't feel threatened by that. But what I will say to you, How do I know this? Because if you have a galvanic reaction between implant and abutment, gold abutment, you get this tarnished abutment. And I almost never saw it. And I have these patients going back to 1985, and so I don't see it as a factor.

But coming back to your question, yes, it is an abutment manufacturer's responsibility. A, as an example, I would not use a 2 percent gold, high palladium content metal, and we tell anybody who's using it, even though we have a buffer of a titanium alloy connector, not to use that kind of a product. So I believe it's the abutment manufacturer's responsibility.

DR. REKOW: And who owns the screws?

DR. MARLIN: I'm sorry.

DR. REKOW: And who owns the screws or whatever other attachment devices you might have for an abutment? Is that part of the abutment or is that--

DR. MARLIN: Oh, the screws and everything that connect--the implant itself is strictly a fixture with an internal thread. From that standpoint, it's a done deal.

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It's a titanium root. Everything else is abutment.

DR. REKOW: Thank you.

DR. GENCO: Further comments, questions?

[No response.]

DR. GENCO: Okay. Thank you very much, Dr.

Marlin.

DR. MARLIN: Thank you.

DR. GENCO: Okay. We'll break now for lunch, and we'll come back at 1 o'clock. I'd ask David Cochran to have had his lunch and be prepared to present at 1 o'clock.

[Whereupon, at 12:22 p.m., the meeting was recessed, to reconvene at 1:00 p.m.]

AFTERNOON SESSION

[1:00 p.m.]

DR. GENCO: Are the people from Strauman USA ready? If so, I'd like to introduce Dr. David Cochran, University of Texas Health Science Center at San Antonio, who represents Strauman USA.

DR. COCHRAN: Thank you, Dr. Genco, and the panel. I appreciate the opportunity to be here with you again today.

As Bob mentioned, I'm professor and chair of the Department of Periodontics in San Antonio, and my expenses have been paid here by the Strauman Company to represent them today, and I'll be the only speaker from this company. I do research and teach and do some consulting work for the Strauman Company, as my disclosure.

I spoke in the November 4th panel meeting, and subsequent to that meeting, the Strauman Company received a letter, as did the other companies, requesting some additional information, and I would like to provide that for you today. The topics that I want to discuss are what was outlined in that letter, and the first one dealt with the safety and effectiveness of the ITI implants in this case, looking at the summary of the coating characteristics, in the case of the ITI implants, TPS.

I was asked by the FDA to look at the clinical results from the life table analysis and failure data. I'm going to provide some information there, compare the success and failure rate to uncoated implants. And I'm just going to mention here today for the sake of time that there is an orthodontic implant, as an implant in another anatomical location, which is made for the palate, a very short implant to help provide orthodontic anchorage, and then just mention a minute special controls.

The ITI dental implant, just to refresh your memory, has been in use since 1974, and there have been over 200 peer-reviewed publications on this system. What these publications document is that the system is a very safe and predictable and effective system for replacement of missing teeth.

Now, the product features of this implant is that it has a single-stage design, as you've heard a little bit about that today. They're both solid and hollow implants. They're made from commercially pure Grade 4 titanium. The portion that goes into the bony part is titanium plasma sprayed. On top of the implant is a machined portion, a transgingival portion, which extends through the connective tissue and epithelium. Inside of the implant, the top of the implant, is a more tapered design to stability the

abutment and the implant. And as mentioned before, there is data both on basic science as well as clinical research that we'll just briefly touch upon today.

When you look at the ITI dental implants, they come as both hollow cylinders as well as solid screw designs, in various lengths, of course, and the cylinders come as both a straight version or what we call a 15-degree angled implant. And the diameter of the solid screws is a standard 4.1 mm thread to thread or 3.3 or 4.8. So there's an option as far as the implants go.

Now, two points about these implants as far as retentive features go. At sort of the gross level or the macro level, on the cylinder implants these are placed with what they call a press fit design; in other words, the implant osteotomy site is slightly less diameter than the cylinder diameter itself. So when you place the implant, you have very tight apposition of the implant into the osteotomy site. You also have two parallel walls there, and then you have these macro retentive holes, is what we call them.

As far as the screw design goes, of course, the threads are there, which provide stabilization as well as increased surface area, as well as force distribution for the implant. So those are sort of the macro retentive

features of the implant.

As far as the more micro retentive elements of the implant, it concerns the surface characteristics of the endosseous portion, which is the titanium plasma sprayed system.

I think it's kind of interesting, too, when we look at the other dental implant companies today. ITI really pioneered the non-submerged approach. So at the time of implant placement, the implant extends beyond the alveolar crest and into the oral cavity. Now several other companies have either made a non-submerged implant, or companies that have traditionally been a submerged company are now placing their implants with an abutment attached at the time of placement. And so the evolution is towards placing implants in a non-submerged approach.

The second feature I'd want to mention is that a roughened implant surface has been used on these implants for over 20 years now, and the reason for that is that there's about 15 years of data to suggest that the roughened implant surface is more osteophilic, if you will. There's more bone-to-implant contact with a roughened surface than there is with a smooth surface. And if you look at the other implant companies on the market today, there's really only one system that doesn't offer their customer a

roughened implant surface.

Now, I want to touch just a minute on the titanium plasma spraying process. We discussed that a little bit earlier, as alluded to, and what happens is that there is an argon gas that's sent through a very intense electric arc, which forms the plasma, hence the name. And the titanium hydride is introduced into this very hot flame of 15,000 to 20,000 degree plasma. Then the particles get accelerated 3,000 meters per second, and this titanium hydride then forms droplets of molten metal. And with the speed that they're accelerated onto the surface of the implant as well as the temperature, the coating is essentially welded to the implant surface.

If you look at the characteristics of the TPS, it's about a 30-micron layer thick by SEM, and what this does is provide a greater surface area than either a polished or machine type implant. Then if you look at some of the measurements using profilometry, you can see RA and RQ values of 6.6 and 8.5 microns. So it's been a well-characterized surface over the years.

What this does is gives us additional surface area for the attachment of bone. Some of the clinicians feel that you can use shorter implants in these cases. You don't need bicortical stabilization because you've increased the

surface area using the TPS. And this same surface has been used over 20 years, so it's a well-documented surface. It's been in vitro tested in a number of different ways to make sure of the consistency and predictability of that surface.

One of the ways that you can measure what the effect of this is to use either histomorphometrics to look at the amount of bone-to-implant contact, or you can use some sort of functional test. In this study by Wilke, this 1990 study, he took either a machine screw or a TPS screw and put this in sheep tibia bone, and he inserted all these screws with 100 newton centimeters of torque. So they all went into the bone at the same torque. Then they waited 24 weeks, and then they measured the amount of torque removal force required to take the screws out of the bone, and you can see that in the case of the smoother surface, the machine surface, it didn't take any more force to get the implant out of the bone as when put in. But when you looked at the roughened surface, it took a lot more force to get the screws out of the bone than used to put in.

So this shows you one of the functional tests that can evaluate the effect that the TPS surface has on implant removal, a functional test for determining bone implant contact. And there are many others that we don't have time to go into today.

Things you should know about the TPS is that the surface oxide layer has the same chemical composition as the surface oxide layer on uncoated machine titanium. So the TPS process itself doesn't alter the oxide layer, which is, of course, crucial to our bodies, what they look it.

As far as corrosion resistance of the TPS goes, really there are a couple properties. It's a passive oxide layer which is stable and inert under physiologic conditions, and this has really been determined through corrosion testing, and what this corrosion test does is simulate a long-term in vivo exposure. And if you analyze the results of this test, they found that there was no dissolution of the titanium after you simulate 35 years' exposure in the body. So it's a very stable and inert process.

If you look at the adhesion of the TPS to the implant body itself, you can see that--what you see is that strength here to remove that is greater than the bond to the bone itself. So the sheer strength of the TPS coating to the implant interface is greater than that of the implant-bone interface. Take-home--and this is done using the standards that are produced for metallurgy in that the TPS is not going to come off the implant surface.

There are controls, as was talked about a little

bit earlier today in some earlier discussions. There are controls done both on the powder that's used to spray onto the surface as well as tests done on the implant once it's been coated. So looking at the titanium hydride, you see the chemical compositions looked at crystalline and grain morphology. Then once it's been sprayed on the implants, it's inspected under electron microscopy. You look for foreign materials in the coating distribution. So there are controls that can be done to assure that things are done in a consistent manner.

Probably what's most interesting to me, then, is the clinical support for this system, and currently the ITI dental implants that are being used, that we're using today, have been marketed since 1984. There has been no change in thread design on the implant. There's no change in the TPS surface. And the take-home is that the currently marketed ones that we use today have been extensively studied over a long period of time.

If we look at some of the literature, and this is going back to studies from 1984 to 1991, I think it's instructive for us to sort of look at these a little bit more in detail than normal. What we've done--you've seen these last time I presented, but what we've done is gone back--because you asked for information on life table

analysis, we put a little star by the ones that have life table analysis. And Baboosh had 484 patients, you can see here, 1,700 implants. These are solid screw implants. Edentulous mandible, eight-year follow-up. Another country, 146 patients, 500 implants, six-and-a-half-year follow-up. High success rates in each case, 88 to 91 percent.

The number of different countries is the point life table analysis, and some of these, whether it be a hollow cylinder implant, hollow screw, or solid screw, all these available, there have been long-term follow-up, and in this case edentulous mandibles, where these implants were first placed, and very high success rates over time. So it's just not one study that you're looking at or one set of patients. You're looking at a number of patients and a number of different implants under various conditions.

If you look at '91 to '94--and I think a point here that needs to be made is that when the Dental Advisory Board made its first recommendation in 1990-1991, they didn't have available all this evidence that we have today. And you guys certainly have a lot more studies at your disposal that you can look at. And this is really when the majority of these papers have been published.

You see, again, large numbers of patients, 156, 84, 126, 33, all the different types of implants that's been

available now since 1984, both fully and partially edentulous, now getting into these implants, various times of follow-up, five years, nine and a half years--again, with high success rates even in ones that are looked at with life table analysis.

If we look at 1995 to 1997, again, a lot of patients have been treated with these implants. A lot of implants have been treated. All the different types that we've seen. So over now probably 20 years we haven't seen problems with the different types of implants. Again, varying times of follow-up, nine-and-a-half years here, two, three years here. But, again, very high success rates, as you've heard earlier today.

Just alone in 1997, more studies, 56 patients here, 12, 109, 1,000 implants here. So it's just not one study that's been looked at. And you look at the follow-up times: seven years, nine years, eight years. There's been not just one study but a number of studies done in different countries, under different indications and different people, with very successful results.

If we look at the one that's--actually not the most recent one just was published by Maritska Stern (ph) on edentulous patients as well, but if we look at the one that's been alluded to a little bit earlier today, here it's

up to eight years. This is done by life table analysis. The analysis is done on three different centers, 1,000 patients, 2,300 implants. Here the number of implants that have been examined in this prospective study--it's a prospective study--up to eight years distribution. And since it has also come up earlier today, at different times of consensus conferences, criteria of success has been analyzed in a number of different articles in the literature. But what was used in this prospective study was what we predominantly use all the time, absence of pain, absence of recurrent infection, mobility, radiolucency, or fracture. So it was very strict criteria that we used to evaluate all these implants at each of the visits.

As the FDA asked about life table analysis, the numbers are presented here for you, and this is the way life table analysis is presented by intervals, of course. And two to three years, after three years you've got 1,219 implants, 98 percent cumulative success rate; four to five years, 500 implants, 96.6 percent implants. And then as these patients get through further time points, they'll be evaluated in this very stringent fashion in a very prospective trial.

So there's plenty of data here, and another thing that was requested was your analysis of your failures. What

we're looking at is we've broken out the data from this one study, and we're looking at the different time intervals here. What you see is in the very first interval, what we call early failures, there was recurrent infection around five implants, eight implants had mobility, for a total of 13 implants out of 2,359 implants that had to be removed.

If you look at the other categories, this is recurrent infections, in other words, infections that were treated and couldn't be resolved, and those implants were taken out. If the implants were mobile, the implants came out. You see that drops off.

Implant fracture, just like it is in all the studies with the ITI implants, there's very few fractures. Progressive bone loss is something we don't see even up to eight years. And even in cases where there's a fair amount of infection, especially as patients lose their plaque control compliance over time, we don't see progressive loss of bone over this time period.

So if you look at these numbers, then, and take all these numbers, you're looking at about 2 percent of the implants that had failures, and the breakdown you can see by category. They're very small percentages in this study.

The way that the infection was looked at at the last examination was when the patients presented for their

last exam, whatever time period that was, if they had any infection around that implant whatsoever, that was considered a failure.

Now, those infections were treated, and some of those implants are going to go on and do very well. But due to the success criteria used, we take the worst-case scenario here with the infection and just say if we add all those up, you're still looking at less than a percent of these implants had any infection around it.

If you look at success by implant type, five-year cumulative success rates, 96 percent; hollow screw was 98 percent; and hollow cylinder was 95 percent. If you look at the data by different parts of the mouth, again, very high success rates. This is the five-year data in the mandible as well as the maxilla.

Also, one of the criteria that are often used for success of implants is that there's less than 1.5 mm of bone loss in the first year of function after loading, and in subsequent it would be less than 0.2 mm of bone loss. This data is not published yet, but from the three different centers it's being analyzed, and you can see that in the first year there's been less than 1.5 mm of bone loss, and in years two to five there have been less than 0.2 average mean bone loss over time.

We were also asked to compare our data to uncoated implants, and if you look at it from the Buser study, which, again, used life table analysis, in the mandible there was about a 97 percent success rate. If you look at Leckholm's (?) data in 1994 in partially edentulous patients, it's 94 percent; in Odell's (?) fully edentulous, it was about 97 percent. So this number compares favorably as well. In the maxilla, about 96 percent; in the Leckholm partially edentulous study, about 92; and Odell fully edentulous, about 87 percent.

What should be pointed out, too, in this comparison is that neither of these studies used life table analysis. And as you know in this room, when you don't use life table analysis, the implants that have been placed in more recently influence the results. And that's why we do life table analysis so you only evaluate the implants at risk during the interval. And so I think when you look at these numbers, these numbers compare very favorably using life table analysis.

So I think what this study does confirm, one of many, as we've shown you, is that the mandibular-maxillary success rates compare favorably with reported Branemark success rates. There are high success rates for hollow and solid implants, and not just from this one study but from

all the different studies I showed you. The ITI implants maintain a high success rate over the long-term follow-up.

As you also know in this room, there are special controls that are available to you if you choose to place these in Class II, as a Class II device. There are a number of special controls that certainly you have available. There are standards for materials. There are standards for lab testing, benchtop testing. There are a number of different guidance documents that the FDA can use for how an implant is evaluated. Good manufacturing practices, the ISO 9001, which the Strauman Company received. And so there are a number of different controls that can be used to make sure that the implants that are sold are reasonably safe in assurance.

So, in conclusion, then, the ITI implant has a consistently high success rate over all anatomical locations. The safe and effective use of the hollow and solid implant plasma sprayed has been confirmed by an extensive body of knowledge. The FDA has sufficient general and special controls to provide reasonable assurance of safety and efficacy. And based upon the clinical and non-clinical results, 200 publications, the ITI system, it is recommended that uncoated and titanium plasma sprayed root form implants be reclassified as Class II devices.

All these numbers are well and good, but I think probably the thing that is most satisfying for me as a clinician is what we do for our patients. And this was a patient that came in, had fractured this tooth off. We extracted the root. We let it heal in, and we came back and placed an ITI dental implant in this area and restored it, and this is a two-year follow-up picture. And I think what you can see is an advantage for this patient in that either of the adjacent teeth were not having to be compromised by being taken down or restored for any sort of reason. And you can have a nice replacement with very pink, healthy tissues.

And in the anterior of the mouth, we have patients that present--this is one of our patients that came and was missing a lateral incisor. This fellow was in his early 20s, had been wearing a partial denture. He got it knocked out in a sporting activity, like a lot of kids do. And we were able to come in here, get rid of the removable partial denture, and provide a restoration that really changes these people's influence.

We have women that come in that will only speak with their hand up at their mouth to hide spaces, and I think when we have the ability to restore these patients, this is really the satisfaction of what we do and hopefully

why we're here today.

Thank you very much.

DR. GENCO: Thank you very much, Dr. Cochran.

Any questions or comments from the panel?

[No response.]

DR. GENCO: Okay. Thank you.

Let's proceed now to the Innova Corporation, Dr. Douglas Deporter and Dr. Robert Pilliar.

MR. KEHOE: My name is Mike Kehoe (ph), and I'm president of Innova Technologies Corporation. I'm just going to mention a few things about the corporation; then I'll turn the meeting over to Dr. Pilliar to speak to the physical characteristics and design of the implant and Dr. Douglas Deporter to speak to the clinical trials.

Innova Technologies is a public corporation headquartered in Toronto, Canada. We have subsidiary offices in San Francisco, California, and Sydney, Australia. We've met the regulatory requirements in Japan, Taiwan, Australia, New Zealand, Canada, and in the U.S. we have both an investigational device exemption and have received 510(k) clearance for sale of the endopore implant in the United States. We also have active research programs in other areas, particularly in oral-maxillofacial surgery, such as a distraction osteogenesis bone plate.

January 1989 was the first human use of the endopore implant at the Faculty of Dentistry, University of Toronto, and in 1992, we received an investigational device exemption from the FDA to conduct clinical trials. In 1994, we received approval from the Health Protection Branch after clinical trials in Canada and the Therapeutic Goods Administration in Australia. In 1995, our 510(k) cleared for the endopore system, but we kept our IDE ongoing with prospective clinical trials. We received approval in Japan in 1996, and as of November 1997, we'd sold about 40,000 implants.

We have continuing clinical trials going on in four countries in six centers, with other 400 patients and approximately 1,100 implants. Right now I think there's 38 publications in peer review journals.

I'd like to turn the meeting over to Dr. Robert Pilliar. He's a professor and director of the Center for Biomaterials, University of Toronto.

DR. PILLIAR: Thank you. I'd like to base my presentation--by the way, for the record, I am a professor at the University of Toronto, Faculty of Dentistry, and the director of the Center for Biomaterials there. I am a co-inventor of this implant system that you will be hearing about, and as such, in accordance with the University of

Toronto policies, I share in some royalties which come back to the University of Toronto for that.

In addition, I also am being paid by Innova for coming down to this meeting today, and also I should state that since this is a public company, I do have some shares in the company. A minor amount.

Now, this is the endopore implant system that I'll be describing to you, and what I wanted to talk about are some of the physical attributes, characteristics of this device, and how they come about through the processing method which is used to make this device.

The rationale for this endopore dental implant is not different from many of the other dental implants that you have heard of today. It's intended to provide reliable implant fixation by bone, in this case ingrowth, into a porous surface region which is formed by a sintering process. And I'd like to just describe that very briefly.

Again, by way of background, I should state that I initially started working on these porous surface implant systems for orthopedic uses back in 1969, and those, in fact, did go into clinical use initially in the late '70s. So there's been along history of these porous surface systems formed by sintering, ones that Dr. Sung has referred to earlier today.

Now, there are many implant systems out there today. Many of them utilize one form or another of mechanical interlock with bone, and I just wanted to note here that what we have here are many designs which contain these macroscopic openings through which bone is intended to grow through, or which have these macroscopic as well as microscopic surface features which are intended to allow for this mechanical interlock of bone and implant. And it's turned out to be a very effective way of stabilizing these devices.

The endopore implant system is made up, as I've mentioned, with this surface region, which is porous, and this is a cross-sectional view of the interface where this coating process--I should emphasize here a coating process is used to create a structure as seen here. What we have, in effect, at that surface region are a number of what I would define a microscopic openings through which bone can grow. So the whole intent, again, is to achieve that type of reliable and mechanical fixation of implant to bone through bone ingrowth in this particular case.

The characteristics of this endopore implant system, it's effectively a cylindrical-type implant system, but with a slight taper angle associated with it. So it's a tapered, truncated cone shape. It's a five-degree taper

angle that you see there.

It's characterized on the surface region by this interconnected porosity which is uniformly distributed through that near surface region. And that I believe is an important and interesting feature of this approach.

The average pore size is around 100 microns or so, and the volume percent porosity which is provided within that surface region is around 35 percent. Most important to recognize is that the result of this sintering operation, after the consolidation of those surface beads or particles which are placed onto the device is a single-piece titanium alloy implant system. In other words, that sintered porous surface region is integrally bonded with the machined, non-porous portion. So after the processing, we have a single-piece implant system. I really think it's important to distinguish that from what I consider a coating, which is one which has an interface which will fail adhesively as opposed to non-adhesively. And I'll mention that very briefly later on.

Some other features of the implant system: It has a smooth, non-porous coronal region, and it comes in a variety of lengths and diameters currently made by Innova Corporation.

Now, the sintering process which is used to form

this porous surface region is a solid state diffusion process. In other words, there's no liquid phase or melting which occurs during that processing. This is the way that we consolidate titanium alloy particles, powder particles, to a bulk form and also to this well-bonded structure to the underlying solid core. And we do that by choosing processing conditions to ensure that we have the required or the desired size, volume percent, and distribution of pores in that surface region. This is done by sintering at 1250 degrees Centigrade in a high vacuum atmosphere furnace, and the end result of that processing is that you have a very strongly bonded surface region where the individual powder particles which are used in the process are well bonded to each other and they're also well bonded to the underlying substrate.

They can be defined and they are characterized by what we define as metallic interatomic bond, so that it's a very strong form of bonding that occurs.

The sinter neck regions, which are the areas of junction between the particles and the particles to the substrate, are substantial; also, the sinter neck zones, when they're examined microscopically, as I'll show you in the next slide, have metallurgical features which are very similar in terms of micro structure. They're the same, in

fact, in terms of micro structure to this neck zone here and the neck zone here. They're very same to the structure that you'd find anywhere in the bulk material. So all this is to say that we do develop this strong metallurgical bond at that junction point after the processing.

So the sintered substrate, surface substrate construct forms a structure with a desirable surface zone network of interconnected pores and channels, and the consolidation of these particles by sintering allows such a structure to be formed, while ensuring the structural integrity of the whole implant component.

Now, this shows you the end result of this type of a structure. This is a histological slide from an early animal study that we undertook to demonstrate how these devices work. And this shows you stained bone tissue which is ingrown into this multi-layered zone here, the surface zone with this interconnected porosity. So we have the ability of the bone to grow into and through these openings, and, in fact, in that manner develop very strong resistance not just to shear forces, which on an irregular or rough surface would develop, but also, interestingly, to tensile forces. We have this three-dimensional interconnection of bone with the porous surface region. This has always been an interesting feature of this approach, of creating these

interconnected surface pores via this process.

Now, the other important aspect of these in terms of characterizing these types of structures is that they have adequate mechanical properties, and we've done that with the implant systems which we form through appropriate interface shear strength tests, appropriate--which, by the way, illustrate that the effective strength of that interface bond, measured in mega-pascals, is in the same range as you would expect for the titanium alloy when you compare shear strengths, for example, and also the fact that the failures which finally do occur when you go to very high loads is a cohesive failure rather than an adhesive failure. So it all, again, speaks to the very strong metallic interatomic bonding which occurs.

Finally, we have also undertaken cyclic testing, interface fatigue testing, again, in shear, and these have been done using a protocol which has ensured that the devices in that surface region will survive loads which are far in excess of those which are expected during in vivo use, up to 5 million cycles, as you see here.

So this is a summary slide, really. What I want to emphasize in terms of these physical characteristics is the fact that this method of processing does result in this single-unit construct with this porous surface region,

which, according to the volume percent, size, and distribution of the pores, is very effective in allowing this type of bony interlock.

Also of interest is the fact that this particular processing method allows us very nice control on those surface zone properties and characteristics and also on the overall thickness of that device. So at this point, Dr. Deporter was going to speak to the clinicals, unless you wanted to have some questions of me.

DR. GENCO: Would you mind, Dr. Pilliar?

DR. PILLIAR: No. That's fine.

DR. GENCO: Does anyone have a question, from the panel?

[No response.]

DR. GENCO: Thank you.

DR. PILLIAR: You're welcome.

DR. GENCO: Dr. Deporter?

DR. DEPORTER: Thank you, Mr. Chairman, members of the panel.

As has been indicated, my name is Deporter. I am a full professor in the Department of Periodontics, University of Toronto. Along with Dr. Pilliar and Dr. Phillip Weston, I'm a co-inventor of what has become the endopore dental implant. There is a patent. It was

assigned to the University of Toronto, and the three of us receive a small percentage of the royalties that are paid to the University of Toronto. Also, since this is a public company, when the company first was formed, I purchased with my own monies a small amount of shares in the company. And, finally, my expenses and a small honorarium are being paid to me for my presentation here today since I'm being taken away from my duties at the University of Toronto.

Now, I am also the first clinician to have used this implant system, and, therefore, I was chosen to present both the data that we've collected at the University of Toronto and also the data that's being presented under the IDE by three American centers.

Now, as you probably know, this implant system was developed with funds from the Medical Research Council of Canada. We began research in 1983, and, of course, we have ongoing clinical trials at the present time. But the first human usage was my and Dr. Watson's investigation, started on a completely edentulous population in 1989, which we treated 52 patients in an identical fashion, in a prospective fashion, each patient receiving three implants in a mandibular over-denture.

At the present time, all of these patients have passed seven years of function, and as you'll see from the

life table analysis, which was requested at the last meeting, I understand, the success rate is somewhere around 93 percent.

We also have ongoing trials in partial edentulism. One set of data is presented on this screen. It's a group of single-tooth patients in the maxilla which I have treated. The majority, if not all, of the patients have passed one year of function. The average functional time at this time is 23 months. The success rate is 100 percent.

Now, the criteria that we've used to assess all implants in all of the trials that we've undertaken, all of the prospective trials we've undertaken, are those published by others, Albrechtson (ph) and others in the literature, so those criteria would be as listed here: lack of clinically detectable mobility of individual unattached implants using manual methods. We've also used the perio test device to detect subclinical mobility or to quantify subclinical mobility, if any. The second criterion is no radiographic evidence of periapical radiolucency. We've gone to the trouble of collecting radiographs as baseline, three months, six months, 12 months, and annual intervals thereafter, using a customized film holder which attaches individually to each implant in order to maximize the opportunity for obtaining the very best possible radiographs. And the

radiographs are then analyzed, examined by a radiologist, Dr. Michael Farrell. So that's the second criterion.

The third criterion would be that after the first year of function, in radiographs there would be less than 0.2 mm of crestal bone loss annually. And the fourth criterion, of course, would be the patient would be in no distress, no signs of recurrent infection or persistent pain or any other symptoms.

Now, in addition to these published criteria, we have also used a series of periodontal parameters, including probing pocket depth, probing attachment level from a fixed reference point, gingival index, plaque index, and sulcular(?) bleeding index upon probing, and we have published this data in 1976 in the Journal of Clinical Perio when all of the patients had passed three years of function. The data presented there shows that they fall within the normal ranges, with teeth in a state of periodontal health, and the data is also very similar to what's been published by other investigators for other implant systems where the implants are in a state of health.

Of course, one never knows how slides will project until the last minute, I guess. This table is perhaps a little bit hard to read, so I'll just lead you through it.

This is a life table analysis for the patients in

over-denture study at the University of Toronto begun in 1989. You see there were 156 implants. That's three implants per patient. Of those 156 implants, five implants failed to integrate--they were all in men--and one implant in a lady. The lady received facial trauma, a direct hit to her implant shortly after re-entry, and that was lost shortly thereafter. So there were six implants lost in the prefunctional period. This is the first time this implant had been used in human beings, and that gave a one-year cumulative success figure of 96 percent.

There were two implants lost from one gentleman slightly after two years of function because of mechanical overload, and another two implants lost slightly after five years in a lady who developed other problems. So this would give a five-year success figure of 94.8 percent, or a cumulative six- or seven-year cumulative success rate of 93 percent. And as I indicated, every one of the patients have passed seven years of function.

So this gives a summary, then, of the results that we've obtained using those criteria that I listed on the earlier slide. We have no clinically detectable mobility, and in fact, a mean perio test value for this group of patients of approximately minus four. Of course, anything below zero is considered to be extremely good. Absent(?)

indicates that there is no sign of periapical radiolucency in any of those standardized, carefully taken films. After the first year of function in which the mean bone loss for the group was basically half a millimeter, 0.45 mm, the overall mean loss of bone annually out to year five was 0.06 mm. So that's about a third of the recommended maximum of 0.2 mm. So certainly we are successful in meeting that criterion. All of the implants are symptom-free, and as you saw with all of the above, there is still a five-year success rate of 93 percent.

At the last meeting, I understand that you were looking for causal factors for implant failure. It's been broken down in this table. There were ten failures, of course, as I indicated. Please focus in on--I think most people are worried about infection with a number of different implant systems. One of the ten implants failed from infection. The others, five were in what has been classified as contraindicated patients because they were heavy smokers, heavy bruxers, and the others basically are one to trauma and the others to mechanical overload.

This represents, just in passing, a group of patients that have received two or more endopore implants in the partially edentulous maxilla. They are part of an ongoing prospective trial for which the average functional

time is 16.5 months. There are 34 patients presented here. The last data was collected December 1, '97. A mean implant length for the whole group was 9 mm, which is significantly less than that generally recommended for the maxilla, 109 implants, and we've lost one. So that gives a 99 percent success at this point.

Now, I don't have a life table analysis for that. I only present that in passing.

The IDE investigations are ongoing in three clinical centers in the United States. There's a mandibular over-denture population in which the identical protocol is used, as we designed for our prospective study at the University of Toronto. There are 92 patients in that study with 275 implants. The average follow-up time is three years. I will show you a life table analysis in a moment. The success rate has been quoted at 94 percent. So basically the same as what we've achieved with our seven-year study in the University of Toronto.

There is also an IDE population of partially edentulous patients, 179 patients, 428 implants, the average functional time two years, and a success rate quoted at 96 percent. Basically the same criteria have been used for assessment of implants as I outlined that we're using in the University of Toronto.

This is a life table analysis for the mandibular over-denture population in the IDE group. You can see again there were 275 implants placed. There were a total of 15 failures. The vast majority of those, 12 of the 15, occurred in the prefunctional period--that is, they did not osseointegrate. After that time, there were only three failures, and they occurred within the first year of function.

Now, as you can see, all of the patients have not passed five years in this group yet, but the mean functional time is three years. The three-year success rate is 94 percent, and basically--well, you can see it doesn't change at all, really, out to the five-year figure. But as I said, fewer patients have passed that point.

This is a life table analysis for the partially edentulous population in the IDE group. Again, I indicated earlier there were 428 implants installed in these patients. As you can see, there were 16 failures, the vast majority of which, nine, failed to osseointegrate. The others, we have a causal table here, I think, as the next slide. Yes.

Now, the causal factors for the losses, these are the causal factors as reported by the three investigators in the three centers in the U.S. that are collecting data for this IDE investigation. You can see, if we're worried about

infection, again, we have one implant that was reported to have failed because of infection of the total number of implants lost. The vast majority were lost for unknown reasons. What that means, I don't know, of course. Those of us who are in implant dentistry realize there are patient-specific factors which sometimes makes it difficult to determine why an implant failed. There are also, of course, operator error issues as well. Unfortunately, seven of those reported were unknown reasons. Then the others basically fall into either--well, one was in a poor location; two were some post-operative pain the patient was complaining about; and the others were for mechanical overloading.

More or less the same result with the partially edentulous data, the causal factors. Five of the 16 implants which failed were reported as unknown reasons, but then the others basically are mechanical overload and two of those 16 failed because of what the operator reported as post-operative infection.

Now, I gather that at the last meeting some questions were asked with regard to if this implant performs equally well in various sites in the jaws, and this is the IDE data which has been broken down into anterior maxilla, posterior maxilla, anterior mandible, posterior mandible in

partially edentulous patients, and you can see that there's basically no difference on site, based on site.

Now, in this cumulative slide--summary slide, rather, of reported cumulative success rates as published in the literature, we've presented some data for the Branemark and for the endopore basically to demonstrate equivalence--the Branemark, of course, being selected because it's the system that's been around the longest, and also because it's the first system to have been proposed for reclassification.

You see the five-year over-denture data reported recently by Jempt (ph) and coworkers for the mandible. It gives a cumulative success figure of 94.5 percent at five years. Our data at five years, which we reported last year in 1997, basically the same, 94.8 percent, or seven years, all of our patients have passed seven years basically unchanged at 93 percent.

So we certainly support, Innova supports and Dr. Pilliar and I as inventors and investigators and experts in this field support the reclassification of endosseous root form dental implants to a type II device. We certainly believe that the endopore qualifies for this reclassification because of the factors listed on this slide. It does have a cylindrical shape. It's made of a

detaining(?) material in size, diameters, and lengths that are typical of the industry, although our lengths are certainly successfully used in much shorter lengths than some other systems.

We use a two-part surgery approach, of course, a screw-fixed hex abutment for prosthetic support. And Mr. Kehoe indicated, there have been more than 40,000 of these implants used worldwide, and certainly the greater than three-year prospective clinical trial studies indicate equivalence with the Branemark system.

Thank you, Mr. Chairman.

DR. GENCO: Thank you, Dr. Deporter.

Are there any questions or comments from the panel? Yes, Leslie?

DR. HEFFEZ: I know that it's critically important to recognize that in the initial year you lose a certain amount of bone around the implant and that thereafter you lose less, but annually you may have a certain loss of bone. One problem I always have is this measurement of 0.2 mm. How does one actually measure 0.2 mm even if the radiographs are taken in a controlled fashion, with no radiographic markers, knowing that the least change will cause a change in your measurement?

DR. DEPORTER: You'll notice that--

DR. GENCO: Excuse me, Dr. Deporter. Could you use the microphone? It's being recorded.

DR. DEPORTER: You'll notice that that is always quoted as a mean value. It's very difficult to measure 0.2 mm on the radiograph. But the criteria that were established by Albrechtson and others was that a mean figure for the group was to be no more than 0.2 mm per year.

DR. HEFFEZ: Right. Which would mean--

DR. DEPORTER: Which would mean that some implants would lose nothing, some would gain, some would lose slight--you know, somewhat more than 0.2 mm. But the mean figure turns out as 0.2 mm. That's the way it's being proposed, so we are simply following the criteria used and established in the literature.

It's difficult to do, off course.

DR. HEFFEZ: I think it probably would be wiser, regardless of who establishes it, to recognize per implant what can be measured and what is significant rather than--

DR. DEPORTER: Well, the significant factor is whether it's progressive. And so you can tell that over a five-year period, for example. There's a recent paper by Ruse (ph) which addresses this I think in a little bit more rationale way, Ruse, and Albrechtson is also on that paper, where they suggest that one way to get around this would be

to produce a cumulative figure over five years. So that if we met the criteria, then any implant surface that you looked at should not have lost more than 1.8 mm of bone. Correct? Not more than 1 mm in the first year, and not more than .2 mm for the remaining four years.

So they've suggested that one should go through every implant in your trial and make sure that no surface, no implant has lost more than that. And I have done that. And there are, in fact, two surfaces that have approaches 1.8, two surfaces of two implants.

DR. HEFFEZ: See, there's the problem. You're taking a mean figure. You're now saying it's applied per implant, that you shouldn't lose 1.8.

DR. DEPORTER: No, no, that's not what I said. All I said was we were meeting the criteria established in the literature that you should have a mean loss of no more than 0.2 mm per year. This is what's generally accepted. But I think that Ruse's proposal that we should look at each individual surface and basically quantify the number of surfaces that haven't or have lost more than 1.8 mm over a five-year period, which, of course, presupposes that every implant is past five years, which isn't always the case in a lot of investigations, as you've seen today. But that's a more rational way to do it, because it is very difficult to

measure 0.2 mm on a per implant basis. But the important thing is that it isn't progressive on a per implant basis.

DR. GENCO: Further questions? John?

DR. BRANSKI: You mentioned a couple times that some implants failed by overload, and I just wondered what is your sort of operational definition of examining a case and determining that the implant did fail by overload. In other words, how do you determine that that is the actual cause?

DR. DEPORTER: Well, it's by deduction, basically, because certainly in the patients that we have at U of T, they're for the most part extremely compliant with things like home care. If you look at our published plaque index data, for example, it's very low. Gingival indices are very low. Mechanical failure is basically an implant which has been successfully functioning, supporting a prosthesis. The home care has been excellent. There's been no sign of infection, and suddenly the implant loosens.

DR. BRANSKI: Well, would you distinguish that from a case where it failed for unknown reasons? Because you mentioned some that failed for unknown reasons.

DR. DEPORTER: Well, basically, I don't know what those investigators classified--why they said it was unknown. My suspicion is that they might have been

mechanical overload, either during the prefunctional period or the post-functional period. So I don't know what--you know, they just said it was unknown reasons, maybe because they didn't think about it long enough or whatever. But I don't have any unknown reasons in my group of patients. Perhaps I'm being presumptive in calling them mechanical overload.

DR. GENCO: Okay. Thank you very much, Dr.

Deporter.

We'll now have Dr. Jack Krauser, who will speak on implant failures.

DR. KRAUSER: Good afternoon. I'm Jack Krauser. I'm a private practice practitioner, and as a matter of conflict of interest, I am the owner of a 510(k) on dental implants and abutments that are at issue for this panel. However, I am not defending or representing my implant systems or premarket notifications in this short presentation.

At the November meeting, I believe it was Dr. Diane Rekow who had actually asked the presenters and the panel, What did implant failure look like? And as a private practice practitioner, I have been gathering this information on my own patients as well as those that have been referred to me. Having a practice in Florida, we have

a lot of patients that move down to our area, so we've been able to not only track our own cases but colleagues' from other areas of the country. So I'd like to present this information.

By the way, my travel expenses were paid for by myself, and yesterday I participated in the Seramed(?) bone graft panel as one of the clinical investigators, and my expenses were not compensated by them.

This first case was done by myself and my teammates approximately three or four years ago, and I showed these X-rays because I'm not quite sure why these implants are at risk or in a failing mode. You see here a failed device, and on the other side, the implants appear to be reasonably stable, although we have some component discrepancy in this area. As we develop the presentation, we'll discuss these aspects.

As a clinician, I've been doing implants since the early 1980s. We started with Nobel Farmer(?) system and Corvent(?) system, which were available at that time. And I have seen a tremendous improvement from the commercial manufacturers. So as a clinician doing the implants, I want to commend our colleagues from the manufacturing arena as they have improved and made consistent design improvements. With regard to the coated companies, there's consistency and

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reproducibility in those devices. I have done some of the Generation 1 coatings and can attest that they are totally different than what is being reproducibly sold on the marketplace today.

I think surface finishes are much greater. At the time we first started doing implants, they were not even delivered to us in a sterile manner. The Striker Company was the first company to actually deliver an implant in a sterile vial, and they are, interestingly, no longer selling dental implants because they're just focusing on their medical devices.

Interface tolerance, several colleagues have discussed this. I think FDA good manufacturing practices and ISO practices for Europe and other countries demand tolerance on all the parts in devices. Dr. Marlin's presentation discussing components for other implants addresses that issue, and I believe the manufacturing integrity is at a great level compared to as it's been in earlier days.

A subtle improvement, such as implant drills, the tolerances are also greater, so we as clinicians who are sizing our cases can use an implant drill to give us a predictable osteotomy site.

This particular slide you will see develop as I