

UNITED STATES OF AMERICA

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FOOD AND DRUG ADMINISTRATION

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

OFFICE OF DEVICE EVALUATION

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DENTAL PRODUCTS PANEL

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MEETING

\* \* \*

THURSDAY,

AUGUST 22, 2002

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*This transcript has not been edited and FDA makes no representation regarding its accuracy*

The Panel met at 8:00 a.m. in the Whetstone/Walker Rooms of the Gaithersburg Holiday Inn, Two Montgomery Village Avenue, Gaithersburg, Maryland, Dr. Leslie Heffez, Chairperson, presiding.

PRESENT:

LESLIE HEFFEZ, D.M.D., M.S., Chairperson

KRISTI ANSETH, Ph.D., Member

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PRESENT (Continued):

PETER BERTRAND, D.D.D., Consultant

RICHARD BURTON, D.D.S., Consultant

DAVID COCHRAN, D.D.S., Ph.D., Member

JAN E. FAULK-EGGLESTON, D.D.S., Consultant

ELIZABETH R. HELMS, Patient Representative

EDMOND R. HEWLETT, D.D.S., Member

ELIZABETH HOWE, Consumer Representative

JANINE JANOSKY, Ph.D., Consultant

STEPHEN LI, Ph.D., Consultant

MARK PATTERS, D.D.S., Ph.D., Consultant

ELIZABETH DIANE REKOW, D.D.S., Member

DANIEL SCHECHTER, J.D., Industry  
Representative

JON B. SUZUKI, D.D.S., Ph.D., Member

PAMELA D. SCOTT Executive Secretary

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P-R-O-C-E-E-D-I-N-G-S

(8:04 a.m.)

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MS. SCOTT: Good morning, good morning.  
I'd like to welcome everyone to the Dental Products  
Panel meeting.

Before we get into our topic for today I  
would like to introduce our panel, and then I have a  
conflict of interest statement to read into the  
record.

My name is Pamela Scott. I'm the  
Executive Secretary for the Dental Products Panel.

Our Chair is Dr. Leslie Heffez. He's  
Professor and department head of oral and  
maxillofacial surgery at the University of Illinois  
at Chicago.

And as I call out the panel members and  
panel consultants' names, if you could just raise  
your hand so that people know who you are, we have  
Dr. Kristi Anseth. She's Patten Associate Professor  
with the Department of Chemical Engineering at the  
University of Colorado.

We have Dr. David Cochran, who's

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1 Professor and chair of the Department of  
2 Periodontics at the University of Texas, Health  
3 Science Center at San Antonio.

4 We also have Dr. Edmond Hewlett, who is  
5 Associate Professor in the Division of Cardiology  
6 and Restorative Dentistry, University of California  
7 at Los Angeles School of Dentistry.

8 We have Dr. Diane Rekow, who is Director  
9 of Translational Research and Professor of  
10 Orthodontics with the New York University College of  
11 Dentistry.

12 We also have Dr. Jon Suzuki, Professor,  
13 School of Dental Medicine at the University of  
14 Pittsburgh.

15 Our consumer representative is Ms.  
16 Elizabeth Howe. She's Outreach Coordinator with the  
17 National Foundation for Ectodermal Dysplasia

18 Our industry representative is Ms.  
19 Daniel Schechter. He's General Counsel with  
20 Parkell, Incorporated.

21 We also have Ms. Elizabeth Helms, who is  
22 serving as our patient representative for this

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1 panel. She is President of the TMJ Society of  
2 California.

3 We also have Dr. Peter Bertrand, who is  
4 the Director of the Orificial Pain Clinic and  
5 specialty advisor for oral facial pain and TMD with  
6 the National Naval Medical Center.

7 We have Dr. Richard Burton, who is  
8 Professor of Oral and Maxillofacial Surgery with the  
9 Department of Hospital Dentistry at the University  
10 of Iowa Hospital and Clinics.

11 We also have Dr. Janine Janosky who is  
12 Associate Professor, Division of Biostatistics with  
13 the University of Pittsburgh, Department of Family  
14 Medicine and Clinical Epidemiology.

15 We have Dr. Stephen Li, who is President  
16 of Medical Device Testing and Innovations.

17 We also have Dr. Mark Patters, who's  
18 Chair of the Department of Periodontology, College  
19 of Dentistry, University of Tennessee.

20 And we have Dr. Jan Faulk-Eggleston,  
21 Chief of the Oral and Maxillofacial Surgery Service  
22 with the Brooke Army Medical Center.

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1                   At this time 1/11 read into the record  
2                   our conflict of interest statement for the Dental  
3                   Products Panel meeting of August 22nd, 2002.

4                   The following announcement addresses  
5                   conflict of interest issues associated with this  
6                   meeting and is made part of the record to preclude  
7                   even the appearance of impropriety.

8                   The determine if any conflict existed,  
9                   the agency reviewed the submitted agenda for this  
10                  meeting and all financial interests reported by the  
11                  committee participants. The conflict of interest  
12                  statutes prohibit special government employees from  
13                  participating in matters that could affect their or  
14                  their employer's financial interest.

15                  The agency has determined, however, that  
16                  the participation of certain members and  
17                  consultants, the need for whose services outweighs  
18                  the potential conflict of interest involved is in  
19                  the best interest of the government.

20                  We would like to note for the record  
21                  that the agency took into consideration a matter  
22                  regarding Dr. Stephen Li, who reported a past

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1 interest in a firm at issue, but in a matter that is  
2 not related to today's agenda. The agency has  
3 determined that he may participate fully in all  
4 deliberations.

5 In the event that the discussions  
6 involve any other product or firms not already on  
7 the agenda for which an FDA participant has a  
8 financial interest, the participant should excuse  
9 him or herself from such involvement, and the  
10 exclusion will be noted for the record.

11 With respect to all other participants,  
12 we ask in the interest of fairness that all persons  
13 making statements or presentations disclose any  
14 current or previous financial involvement with any  
15 firms whose product they may wish to comment upon.

16 And before I turn it over to Dr. Heffez,  
17 I also would like to introduce Dr. Susan Runner, who  
18 is the Branch Chief of the Dental Devices Branch  
19 within the Division of Anesthesiology, Infection  
20 Control, General Hospital, and Dental Devices.

21 I got that right. We just changed our  
22 division name.

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1 (Laughter)

2 MS. SCOTT: Dr. Heffez.

3 CHAIRMAN HEFFEZ: I'd like to proceed to  
4 the open public hearing. Those who wish to speak  
5 should state their name, state their affiliation,  
6 and any specific financial interest.

7 We've reserved 30 minutes for this  
8 period of time, and I'll ask if there's anybody in  
9 the audience who would like to come to the podium.

10 (No response.)

11 CHAIRMAN HEFFEZ: Nobody had signed up  
12 previously, despite the advertisement of this  
13 meeting, and I don't see anyone coming to the  
14 podium. So we'll proceed then to the industry  
15 presentation.

16 The industry presentation will last one  
17 hour, and I will hold you to the time.

18 MR. PRATT: Good morning. My name is  
19 Joel --

20 CHAIRMAN HEFFEZ: Excuse me. Excuse me,  
21 sir.

22 Prior to your start, I would just want

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1 to have Pamela Scott list the members and who are  
2 voting members for this committee.

3 MS. SCOTT: I apologize. I need to read  
4 into the record those panel consultants who are  
5 deputized to vote during this meeting.

6 Appointment to temporary voting status,  
7 pursuant to the authority granted under the Medical  
8 Devices Advisory Committee charter, dated October  
9 27th, 1990, as amended April 20th, 1995, I appoint  
10 the following people as voting members of the Dental  
11 Products Panel for this panel meeting on August  
12 22nd, 2002:

13 Dr. Peter Bertrand

14 Dr. Richard Burton

15 Dr. Janine Janosky

16 Dr. Stephen Li

17 Dr. Mark Patters

18 Dr. Jan Faulk-Eggleston

19 For the record, these people are special  
20 government employees and are consultants to this  
21 panel under the Medical Devices Advisory Committee.  
22 They have undergone customary conflict of interest

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1 review. They have reviewed the material to be  
2 considered at this meeting.

3 Signed, David Feigal, M.D., Director,  
4 Center for Devices and Radiological Health, August  
5 19th, 2002.

6 Thank you.

7 CHAIRMAN HEFFEZ: Mr. Pratt, you may  
8 begin.

9 MR. PRATT: Thank you.

10 Good morning. I am Joel Pratt with  
11 Lorenz Surgical, and I will briefly show you a  
12 couple slides to start our presentation.

13 This is sponsored by Biomet,  
14 Incorporated. Biomet consists of a number of  
15 different subsidiaries that address different  
16 orthopedic and musculoskeletal specialties. So  
17 within that framework, as you can see by the  
18 customers and their specialization, this would be  
19 considered a Lorenz product.

20 Attending today from management are  
21 those listed from both Biomet and from Lorenz,  
22 several of whom will be speaking. We have two

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1 clinicians present: Dr. Peter Quinn from  
2 Philadelphia, Pennsylvania, and Dr. Douglas Sinn  
3 from Dallas, Texas.

4 We are asking approval for the Lorenz  
5 TMJ, which is a total joint replacement for the  
6 temporomandibular joint, and the indications we are  
7 pursuing are arthritis, malignancy, benign  
8 neoplasms, functional deformity, revision  
9 procedures, avascular necrosis, ankylosis,  
10 degenerated or resorbed joints, fracture, multiply  
11 operated joints, and developmental abnormality.

12 MR. ROMAN: Good morning. My name is  
13 Shawn Roman, and I am the development engineer  
14 currently working with the TMJ total joint  
15 replacement system at Walter Lorenz Surgical.

16 I will be presenting a description of  
17 our device, as well as a summary of all of the  
18 mechanical testing that has been performed.

19 The TMJ total joint replacement system  
20 is a two component system that comprises mandibular  
21 fossa components, as well as a glenoid fossa  
22 component. The purpose of the fossa component is to

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1 replace the glenoid fossa of the temporal bone.

2 Our fossa components are machined from  
3 ultra high molecular weight polyethylene and are  
4 offered in three sizes, small, medium, and large,  
5 both the right and left side anatomy.

6 We currently offer two different designs  
7 in the sizes mentioned. The original design  
8 included a post on the superior surface of the  
9 implant. We added a second design without the post  
10 in February of 2002, and both designs are secured to  
11 the zygomatic arch using self-tapping, two  
12 millimeter diameter fossa screws made from Titanium  
13 64 alloy. We also offer 2.3 millimeter diameter  
14 crews as emergency screws.

15 This slide shows the difference between  
16 the two designs. The design on the left obviously  
17 has a small post protruding from the superior  
18 surface of the implant. This post was included in  
19 the original design to act as an additional  
20 anchoring method when using bone cement or other  
21 approved cranio-maxillofacial filler materials to  
22 fill voids between the fossa prosthesis and the

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1           glenoid fossa bone.

2                         Both designs include an undercut groove  
3           on the superior surface of the implant, which also  
4           offers a securing area for bone filler material.

5                         So, therefore, both designs can be used  
6           with or without filler material. It has been found  
7           that the design without the post is easier to place  
8           and requires the removal of less bone.

9                         The purpose of the mandibular components  
10          is to replace the articulating mandibular condyle  
11          located at the proximal end of the mandibular ramus.

12                         We currently offer three different  
13          designs or -- I'm sorry -- our mandibular components  
14          are machined from cobalt-chromium-molybdenum alloy.  
15          The ramal portion of the mandibular component has a  
16          roughened titanium plasma spray coating on the  
17          medial surface. This plasma spray coating consists  
18          of the Ti-64 alloy.

19                         We currently offer three different  
20          designs: a standard, narrow, and offset. I will go  
21          into these in a little bit more detail with the aid  
22          of some slides, but all three designs are offered in

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1 five different sizes for both the left and right  
2 side anatomy.

3 We started with the narrow design, added  
4 the standard design in January of 2000, and added  
5 the offset design in February of 2002.

6 All three designs are secured to the  
7 mandibular bone using self-tapping 2.7 millimeter  
8 diameter mandibular screws made from Ti-64 alloy.  
9 The 3.2 millimeter diameter screws are offered as  
10 emergency screws.

11 Here you can see the difference between  
12 the standard design and the narrow design. As I  
13 mentioned, we started with the narrow design. We  
14 added the standard design in January of 2000 to add  
15 additional screw hole options to allow for placement  
16 of the mandibular screws in the best bone possible.

17 This slide shows the difference between  
18 the standard design and the offset design, the only  
19 difference being that on the standard design the  
20 spherical head is offset to the medial side of the  
21 ramal plate. In the offset design, the spherical  
22 head is offset to the lateral side of the ramal

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1 plate.

2 The offset design was added to allow for  
3 medial lateral or to accommodate for medial lateral  
4 discrepancies between the fossa components and the  
5 mandibular components.

6 This is a list of a summary of all the  
7 testing that was completed, all of the mechanical  
8 testing completed on these joints. I won't cover  
9 these in detail here because I discussed them in  
10 detail throughout the rest of the presentation.

11 Basically we performed three different  
12 series of fatigue testing to insure that the  
13 mandibular fossa construct could withstand the  
14 loading seen in the TM joint.

15 The same testing protocol was used for  
16 all three series of testing. Basically the protocol  
17 consisted of cyclic compressive testing, compressive  
18 loading of the mandibular component against the  
19 fossa component.

20 We incorporated three different  
21 conditions into the testing protocol to simulate  
22 worst case situations. First of all, the mandibular

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1 component was secured below the center line of the  
2 first screw hole to simulate a patient with a large  
3 portion of the ramus removed or missing.

4 The mandibular component was also tilted  
5 at ten degrees to induce a large bending moment in  
6 the ramal plate, and we selected a maximum load of  
7 145 pounds because this loading was documented in  
8 the literature to be the loading seen in patients  
9 with normal musculature that had not undergone  
10 previous TMJ surgeries. This load would obviously  
11 be excessive for patients who had undergone TMJ  
12 surgery.

13 This is just a schematic of the test  
14 set-up. The mandibular component was potted to the  
15 bottom test fixture, fossa component potted to the  
16 top test fixture. The bottom test fixture was held  
17 stationary while the top test fixture was cycled at  
18 ten to 30 Hertz.

19 I included this slide just to show that  
20 there was clearance milled into the top test fixture  
21 to allow or to accommodate for the post on the fossa  
22 component. The area around the post was -- there

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1 was bone cement placed in the area around the post  
2 to simulate surgical application in all of the  
3 fatigue testing done.

4 In the first series of fatigue testing,  
5 we tested the original design of the components,  
6 tested five different joints. All of the five  
7 joints made it out to ten million cycles with no  
8 failures.

9 Although in this first series of testing  
10 bone cement was used, the condition of the bond  
11 cement after the testing was not documented. So we  
12 ran a second series of fatigue testing that looks  
13 specifically at the effects of fatigue on the bone  
14 cement.

15 Another five samples were tested. All  
16 five of the joints made it through ten million  
17 cycles with no failures, and there was no  
18 fragmenting or chipping of the bone cement noted.

19 The third round of fatigue testing  
20 looked at design enhancements that were made to the  
21 mandibular components. These design enhancements  
22 included adding the titanium plasma spray coating to

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1 the medial side of the implant and also increased  
2 the screw holes slightly in diameter.

3 Another five samples were tested.  
4 Again, all five samples made it to ten million  
5 cycles without failure.

6 We performed static testing on the  
7 mandibular component to determine the amount of  
8 force required to fracture the condylar neck of the  
9 design, and in this testing the mandibular component  
10 was fixated to bovine tibial bone using four 2.7  
11 millimeter diameter mandibular screws.

12 A direct force, direct Allen force was  
13 then applied to spherical head until failure of the  
14 component. The failure mode that was seen was not  
15 fracture of the condylar neck, but rather the neck  
16 portion bent with no breakage at 576 pounds.

17 This loading or these results were  
18 deemed acceptable because this loading is three and  
19 a half times larger than the 145 pounds joint  
20 loading discussed earlier in the fatigue testing.

21 We also performed pull through testing  
22 on the fossa screws to determine the amount of force

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1 required to pull them through the fossa flange. In  
2 this testing, test specimens representing the fossa  
3 screws were pulled through a polyethylene sheet made  
4 of the same material as the fossa component. This  
5 polyethylene sheet was the same thickness as the  
6 fossa flange.

7 Basically a downward force was applied  
8 to the test specimens until they were pulled through  
9 the polyethylene.

10 This just shows that there was clearance  
11 underneath the fixture to pull those test specimens  
12 through.

13 They pulled through at an average load  
14 of 80 pounds. This was deemed acceptable because  
15 this was well above what would be seen in vivo.

16 We also performed compressive testing on  
17 the fossa flange to determine the amount of force  
18 required to fracture the flange. In this testing,  
19 we attached the fossa component to wooden blocks  
20 using only two of the 2.0 diameter fossa screws.

21 A direct force was then applied to the  
22 articular surface of the fossa component.

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1                   This is a close-up just showing that we  
2                   simulated a worst case by not supporting the side of  
3                   the fossa component opposite the articular surface.

4                   The failure mode that was noticed during  
5                   this testing was, again, not fracture of the fossa  
6                   or fossa flange, but rather the fossa flange  
7                   collapsed or bent at an average load of 83 pounds.

8                   This, again, was deemed acceptable  
9                   because this was a worst case test in vivo that you  
10                  would have the support of the temporal bone on the  
11                  side opposite the articular surface.

12                  The final mechanical testing that was  
13                  performed was pull-out testing on the 2.7 millimeter  
14                  mandibular screws. In this testing, the mandibular  
15                  screws were inserted through a test fixture into  
16                  bovine cortical bone. Then an upward force was  
17                  applied to the test fixture until the screws were  
18                  removed from the bone.

19                  This occurred at an average pull-out  
20                  strength of 373 pounds. This, again, was deemed  
21                  acceptable because this loading was well above what  
22                  would be seen in vivo.

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1                   So in summary, we performed three  
2                   different series of fatigue testing with a total  
3                   number of 15 joints. All 15 joints made it to ten  
4                   million cycles without failure. In the static  
5                   testing of the mandibular component condylar neck  
6                   bent at an average loading of 576 pounds.

7                   The pull through test on the fossa  
8                   screws showed an average pull through strength of 80  
9                   pounds. The compression of the fossa flange showed  
10                  that the fossa flange bends at an average of 83  
11                  pounds, and on the pull-out testing of the 2.7  
12                  millimeter screws, there's an average pull-out of  
13                  373 pounds.

14                  DR. QUINN: Good morning. My name is  
15                  Peter Quinn. I'm the Chairman of Oral Surgery at  
16                  University of Pennsylvania, and along with Doug Sinn  
17                  I'd like to stand for a second.

18                  We performed the majority of the  
19                  surgeries in this study. Doug is the Chairman at  
20                  the University of Texas Southwest in Dallas.

21                  While I'm waiting for this to boot, I  
22                  thought what we might do is look at some of the

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1 surgical aspects of this joint because I think it  
2 will help us to understand the development, and I  
3 know there are three surgeons on the panel, but for  
4 the non-surgeons, I thought it would be helpful to  
5 look at the unique aspects of this joint which  
6 actually have implications for how it was designed.

7 We began the design process in 1991 and  
8 enrolled the first patient in 1995. This is the  
9 prosthesis with the polyethylene fossa and cobalt  
10 chrome ramal component.

11 I would just like to point out at the  
12 beginning the reasons for pursuing this is that we  
13 feel strongly that a prosthetic joint does have  
14 advantages, and on the left they really are in terms  
15 of a quality improvement standpoint lack of donor  
16 site morbidity, reduced intraoperative time, a  
17 potential for decreased hospitalization, and  
18 immediate functional ability as opposed to grafts,  
19 autogenous grafts.

20 Also, you can maintain the occlusion or  
21 actually change it as you'll see, which is an  
22 opportunity you get with a prosthesis over an

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1 autogenous graft, the opportunity to manipulate the  
2 design to discourage heterotopic bone formation, and  
3 again, the opportunity to correct occlusion.

4 These I think are extremely important  
5 because we still do a large number of autogenous rib  
6 grafts in children, and we believe that that is the  
7 procedure of choice in the skeletally immature  
8 patient.

9 In the skeletally mature patient with an  
10 acceptable indication, we think there should be a  
11 safe and efficacious stock prosthesis. We also  
12 believe firmly that in patients who are anatomically  
13 mutilated, who have undergone multiple operations  
14 where this stock prosthesis or any would not be  
15 appropriate, we use a CAD-CAM 3D construction by TMJ  
16 Concepts, which we also think is a very safe and  
17 effective prosthesis.

18 The relative contraindications for the  
19 alloplastic joint is allergy, and we'll see we've  
20 had two patients with nickel allergy where we have  
21 FDA approval to use titanium instead of cobalt  
22 chromium; chronic infection; skeletal immaturity, as

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1 I've mentioned; and any systemic disease that would  
2 increase the risk of infection.

3 Now, briefly, and I usually talk fast,  
4 but I'll talk faster today, I just wanted to show  
5 you the unique aspects because I do think after 22  
6 years I have been humbled by this joint. It is a  
7 unique joint in its mechanics and also in terms of  
8 its approach because when I watch my orthopedic  
9 colleagues, they're able to make bigger incisions  
10 and see the entire construct.

11 We are always working in a tunnel  
12 between the facial nerve, and the other issue we  
13 have to deal with is the vasculature. So this is a  
14 standard procedure with a modified face lift or  
15 rhytidectomy incision to place the fossa in a  
16 posterior mandibular incisions, to place the ramal  
17 component.

18 I'm going to go through these just  
19 because I do think after Shawn's presentation we can  
20 understand the design based on the surgical  
21 technique, and once the preauricular and posterior  
22 mandibular incisions are made, I think the first

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1 thing you will note is the thickness of the fossa  
2 which is dictated by the minimal thickness that you  
3 can have in polyethylene to have sufficient wear  
4 resistance.

5 That does push condylion, which is the  
6 point of rotation. The normal condyle is higher,  
7 and you'll see in some radiographs that it just  
8 pushed that point out.

9 It also means that we remove more bone  
10 in the superior surface than other joints. This is  
11 a standard condylectomy osteotomy cut. This  
12 actually is still performed for ankylosis where the  
13 condyle is just removed and nothing is replaced,  
14 which we don't think is indicated.

15 In this joint we use a two-step  
16 osteotomy where we remove the upper part of the  
17 condyle. Then in the space created by that cut, we  
18 push the ramus up, which is a safer way of removing  
19 further bone, to accommodate the fossa, and in  
20 multiply operated patients, we remove the coronoid  
21 because it gives them a greater opening.

22 Special instruments have been designed,

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1 and thee are condylar retractors, and what these are  
2 protecting against is the internal maxillary artery  
3 that runs medial to the neck of the condyle, and  
4 these are designed to avoid any damage to that.

5 Here's a standard cut through an  
6 ankylose joint, and you can see we don't like to  
7 instrument more inferior here because of the facial  
8 nerve that's coming through the junction of the  
9 auricle. So what we do is remove the upper portion.

10 The lower incision has been made. You  
11 can just see the hint of it here, for two reasons.  
12 If there's any bleeding, we can control it from the  
13 lower incision by ligating branches of the carotid.

14 And, secondly, once this portion is  
15 moved, we literally move the ramus up and remove  
16 what other additional bone may have to be removed to  
17 fit the fossa.

18 As Shawn said, this is an ultra high  
19 molecular weight polyethylene in the fossa. It was  
20 designed to have maximum mating between the condyle  
21 and the fossa. Remember this is a ginglimal,  
22 arthrodial joint that both rotates and translates.

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1 Prosthetic joints only rotate because we are going  
2 to remove the lateral pterygoid head.

3 I'm going to talk about the PMMA because  
4 it was used early in the study. We have not place  
5 PMMA cement after 1998. What we did in the early  
6 cadaver studies when we designed the joint was found  
7 that over 70 percent of the variability in the human  
8 temporomandibular joint is in the articular  
9 eminence

10 So this implant is designed to flatten  
11 the articular eminence, and there are specially  
12 designed burrs to do that, which flatten the  
13 articular eminence to give you tripod stability of  
14 the fossa implant.

15 And here is an articular eminence that  
16 has been flattened, and as you'll see, the burr was  
17 designed not only to take the eminence off, but to  
18 give you the radial curve of the implant itself.

19 This is a fossa and the condyle in  
20 position. In terms of timing, we actually place the  
21 fossa, and then go back and put the patient in  
22 fixation, and this is, again, what's unique to this

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1 joint as opposed to orthopedic joints.

2 Here's a picture of the fossa with the  
3 burr design, and this was one of the major reasons  
4 why we're able to discontinue the use of the cement  
5 because after the fit got better and better with  
6 time, we were using less than one cc of PMMA, and it  
7 did not seem to be appropriate to continue its use.

8 These are sizers, and this fossa is in  
9 three different sizes. What is uniform is the  
10 articulating surface. This doesn't change.

11 What does change is the number of  
12 preconstructed holes to give you options in the  
13 zygomatic arch.

14 Again, in the beginning of this study,  
15 we were approved to use PMMA only for void filling.  
16 Our original intent was to ultimately replace it,  
17 but we have stopped using it completely because it  
18 was designed in the beginning -- this is one of the  
19 first devices we used in the laboratory. You can  
20 see what the peg was used for in terms of retention.  
21 Other than that it has no role.

22 So once the fossa is placed in position

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1 we then put the patient in fixation. This is work  
2 done in the Netherlands in 1993, which determined  
3 that if you move the point of rotation inferiorly  
4 -- and these are cadaver studies that we first did  
5 in 1992 -- there was some pseudo translation. The  
6 jaw is being opened on the right, and you can see  
7 there's almost a ramping, gliding effect of this  
8 prosthesis, which is not true translation which you  
9 can only get with a lateral pterygoid muscle.

10 In this slide you can see these are TMJ  
11 implants incorporated. This is a metal to metal  
12 joint that had to be removed because of metallosis  
13 and foreign body reaction, but what you see is when  
14 it's replaced with the Lorenz, that you've lowered  
15 the point of rotation. If you compare where a  
16 normal condyle and even this prosthetic condyle  
17 seats in an inferior/superior component.

18 The condylar component, again, is a  
19 cobalt chromium. It's secured with 2.7 millimeter  
20 screws. This is the narrow design, and we have both  
21 designs because we do see a patient population who  
22 on the average has over five surgeries, and some as

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1 many as 29 surgical procedures.

2 In those cases we did come up with a  
3 broader footplate here to give us more options to  
4 put screws because in some of these rami there are  
5 multiple screw holes. There's damage to the  
6 cortical bone from previous rib graphs.

7 You can see an ankylose joint here  
8 that's been replaced with the standard design. This  
9 is the approach to place the lower component or the  
10 condylar component, and you can see we get complete  
11 visibility of the ramus, and we can place all of the  
12 screws through this lower incision.

13 The other aspect that Shawn mentioned is  
14 this Swan neck design, and this does differ from all  
15 of the -- some of the other prosthetic joints that  
16 have a right angle, a 90 degree bend at the condylar  
17 head, and that somewhat assumes that you can predict  
18 where the osteotomy cut will be, which is usually  
19 not the case.

20 This allows you to have some medial  
21 lateral change by moving this condylar up and down,  
22 and it allows you to change the medial lateral

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1 position somewhat by altering the bone at the  
2 superior edge of the ramus.

3 It's in contrast to some other joint  
4 prostheses that have been used. Briefly, this is  
5 the Kent-Vitek. This was Synthes. This is Delrin  
6 Timesh. This is Christensen I, with an acrylic  
7 head, and Christensen 11, with an acrylic head. And  
8 you can see part of the difference is the  
9 angulation, and this mimics the angulation of the  
10 normal condyle at approximately 20 degrees.

11 So the mating is spherical. We made the  
12 condylar head as large as possible to give us a  
13 greater surface area for the load distribution.  
14 These are the templates we use to determine what  
15 size condylar component we'll use.

16 And you can see here a patient who has  
17 had -- this patient actually had 16 operations.  
18 These are two failed rib graphs that you can see  
19 have detached completely from the ramus and are free  
20 floating, and this is the wider design because in  
21 these patients who have had multiple surgery, we  
22 sometimes wind up with poor quality cortical bone on

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1 the ramus.

2 The current available lengths of the  
3 prosthesis are 45, 50, and 55, and this is the  
4 standard design. What this allows you to do is if  
5 there's damage to cortical bone with a preoperative  
6 X-ray that you can determine where the inferior  
7 alveolar nerve is, you are able to place screws  
8 anterior and posterior to the nerve and find better  
9 cortical bone where it has been destroyed by  
10 previous surgery.

11 Again, after the fossa is placed, we  
12 place the patient into intermaxillary fixation  
13 because there is very little leeway in the placement  
14 of these joints. In my clinical experience, there's  
15 about 25 to 30 percent of the time we literally  
16 change the position of the condyle after checking  
17 the occlusion and the range of motion.

18 It's originally placed with two screws  
19 only, and if you remember, the other unique thing  
20 here is we are in and out of the mouth. We're in  
21 and out of from a sterile to a non-sterile field.

22 So we place the condylar prosthesis

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1 tentatively, check the range of motion, and then  
2 only secure it when we're happy with it. We have  
3 designed some special sterile mandibular  
4 manipulators that allow the surgeon to move the  
5 mandible and check the actual mechanics of the  
6 joint, but it clearly has to be checked before the  
7 final screws are placed in the condylar prosthesis.

8 This is a patient who is four months  
9 out. You can see these rhytidectomy incisions can  
10 be hidden rather well in the preauricular crease and  
11 in the post mandibular crease.

12 Lastly, just an example of a patient,  
13 the type of patient we see. This is a 28 year old  
14 male who had bilateral condylar fractures as a  
15 child, I would guess anywhere between seven and  
16 eight years of age, just given the retrognathia. He  
17 is completely fused. There's no oral opening at  
18 all.

19 He's had four operations. Most of them  
20 are gap arthroplasties, which **is** the standard way of  
21 just going in and cutting it, all of which refuses.  
22 And you can see he's completely fused to the base of

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1 the skull.

2 This is a case where even though we used  
3 a lot of custom joints, even this one, I think,  
4 would be difficult because it would be difficult to  
5 somewhat predict exactly where your surgery cuts  
6 would be because of the massive amount of bone here  
7 that is fusing him to the base of the skull.

a The other thing we mentioned earlier is  
9 the ability -- and you only have this ability with  
10 bilateral prostheses. You can't do it with the  
11 unilateral prosthesis - is to change the occlusion.  
12 Once the mandible is freed, if you're going to place  
13 bilateral joints, you can bring the mandible  
14 forwards or backwards, and you can change the  
15 preexisting occlusion, which I think is a major  
16 advantage of prosthetic joints.

17 And you can see here that we do remove  
18 large amounts of bone because we do have concern of  
19 heterotopic bone. When I discuss adverse events,  
20 you'll see our reasonable goal for entrance size of  
21 opening is approximately 30 to 33. Remember normal  
22 opening in an adult can be 45 to 53. We don't

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1 achieve that because these joints only rotate. They  
2 don't translate.

3 So that's what we think **is** a reasonable  
4 outcome. We have complications just briefly. I'll  
5 show you the two that I think are most vexing, but  
6 you'll see the numbers are more than acceptable --  
7 is infection. This is a fistula that has  
8 developed. The fossa had to be removed, and after a  
9 protracted course of IV antibiotics, we were able to  
10 reinsert one.

11 That's not always the case, as I'll show  
12 you later, and I think one of the most difficult  
13 problems we have is heterotopic bone, as the  
14 orthopedic surgeons do as well. This is a young  
15 African American female who has got horrific  
16 keloids, and I think that heterotopic bone and  
17 keloids are simply analogous genetic aberrations in  
18 soft tissue and bone.

19 But we placed a prosthesis in her, and  
20 you can see she has completely fused to the base of  
21 the skull. This is a very difficult problem.

22 Actually this patient has had a revision

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1 where we removed the prosthesis, removed the bone,  
2 and in this patient we've radiated her with 1,000  
3 rads of radiation over five days, and she seems to  
4 be doing very well, maintaining an opening of about  
5 26 millimeters at this time.

6 So that's a quick overview of the  
7 clinical application, and do you want me to start  
8 the other one?

9 And Mary Verstynen, whom I'd like to  
10 introduce, is the Director of Clinical Affairs of  
11 Biomet, who has also been my monitor and guiding  
12 light. We are going to kind of off and on give you  
13 the statistical results of the study.

14 MS. VERSTYENEN: The clinical  
15 investigation will be presented by Dr. Quinn and  
16 myself, and please note the handouts that you have.  
17 We have done an abbreviated form of this slide  
18 presentation in order to keep with the time frame  
19 required,

20 In 1994, an IDE was submitted to the FDA  
21 for a prospective multi-center clinical trial. It  
22 was designed to document patient improvement from

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1 baseline to postoperative visits. In other words,  
2 the patient was serve as their own control.

3 The patient population was purposely  
4 defined very broadly. There were very few  
5 exclusions, and the inclusions are listed on this  
6 slide with unilateral and bilateral cases being  
7 used.

8 There were multiple diagnoses that were  
9 included within the study protocol. One of the only  
10 exclusions or one of the few exclusions was the  
11 patients had to be skeletally mature, but most  
12 importantly, the patients had to be selected after  
13 nonsurgical treatment failure or previous implant  
14 failure.

15 A study design included collection of  
16 baseline data, operative data, and follow-up data.  
17 The follow-up data as listed ran from one month to  
18 three months or three years, with the three years  
19 being a study endpoint, and this was based on an **FDA**  
20 draft guidance document that was available at the  
21 time.

22 The primary efficacy assessments as

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1 defined in the protocol were jaw pain intensity,  
2 interference with eating, and MIO. The jaw pain  
3 intensity and interference with eating were  
4 collected on ten centimeter **VAS** scales which went  
5 from zero to ten with zero being either no pain or  
6 no interference with eating, and ten being worst  
7 case.

8 The MIO was collected in terms of  
9 millimeters. Additional efficacy assessments  
10 included occlusion and anterior open bite, cross  
11 bite, and wound healing.

12 Safety assessments were documented as  
13 adverse events, device related or otherwise, and in  
14 addition, radiographic assessments were collected at  
15 each of the follow-up time periods which are listed  
16 as follows.

17 The position of implants were compared  
18 to immediate post-op, and then additional X-ray  
19 findings.

20 We also defined patient and study  
21 success, which will follow on the next slide, and in  
22 addition, we identified primary efficacy endpoints

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1 and secondary efficacy endpoints.

2 The study was based on improvement from  
3 baseline to three years. So the primary efficacy  
4 endpoint was the difference between baseline and  
5 three years for pain, interference with eating, and  
6 MIO.

7 And then in addition, the secondary  
8 endpoints looked at the same pain interference with  
9 eating and MIO at baseline and then at each of the  
10 individual follow-ups.

11 In addition, we included as a secondary  
12 efficacy endpoint patient satisfaction, which also  
13 included a question of whether or not the patients  
14 would be willing to have the surgery again.

15 Patient success is defined as follows  
16 with patients having to meet both criteria to be a  
17 success. In order to be a success, they had to have  
18 no permanent joint removal in two of the following  
19 three assessments, which were the primary efficacy  
20 endpoints.

21 There had to be a one centimeter  
22 reduction in pain from baseline to three years

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1 and/or a one centimeter reduction in eating also at  
2 the same time frame, and an increase of MIO of ten  
3 percent once again from baseline to three years.

4 A study success was determined that if  
5 60 percent of the patients met the success criteria,  
6 the study would be a success.

7 The statistical plan analyzed three  
8 different groups of which there were two cohort  
9 groups and the total study group which was comprised  
10 of 180 cases and 256 joints.

11 The first cohort group is the cohort  
12 unimputed group, which included 45 cases which  
13 actually had follow-up at the three-year time frame.  
14 The cohort imputed group included those 45 cases,  
15 plus imputed data from the closest follow-up time  
16 point to the three years but not past it.

17 So if a patient was seen at the one-year  
18 time point and wasn't seen at three years, we would  
19 input the values for that.

20 In addition, the statistical plan  
21 outlined that we would do T test analysis and  
22 repeated measures analysis for the primary and

1 secondary endpoints, and we also would do subgroup  
2 covariate and multivariate analysis.

3 Dr. Quinn will take over from here now  
4 with the baseline findings and the following tables  
5 will show the cohort and the total groups to show  
6 how comparative these groups were.

7 DR. QUINN: And, again, I think it is a  
8 unique patient population. These are multiply  
9 operated patients. There are some unique  
10 characteristics that tend to be similar to other  
11 joint studies. So it wasn't that this study was  
12 different than other TMJ findings, but there is some  
13 unique characteristics of that patient group.

14 The mean age -- and, again, I'm going to  
15 try to point out the similarities in the total group  
16 and the cohort group -- was 40.2 and 37.8. The  
17 gender follows most TMJ studies, and I'm not sure  
18 anyone has a good explanation, but they are usually  
19 close to 90 percent female. There's mechanical  
20 reasons for that because of the differences in Type  
21 II collagen between men and women, and there are  
22 some biochemical discussions about estrogen

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1 receptors that may affect some of the issues, but  
2 this is clearly consistent with other studies.

3 The sidedness broke out relatively even  
4 between unilateral and bilateral. It was almost 50  
5 50 in between right and left side.

6 The majority of the cases, as I've  
7 mentioned, they were done between Dr. Sinn and I,  
8 and in the cohort group, it broke out around the  
9 same percentages.

10 The baseline medical history, again, is  
11 somewhat similar for these group of patients, and  
12 again, as I mentioned before, these are humbling  
13 patients because the criteria for success that Mary  
14 mentioned, I think one of the reviewers said we had  
15 somewhat lenient criteria for success. I think it  
16 was based pretty much on our experience with these  
17 multiply operated patients. **As** you'll see, we far  
18 exceeded those criteria for success, as we'll see  
19 later on.

20 We used a Wilkes classification, which  
21 is named after Clyde Wilkes, which actually just  
22 classifies according to pain, restriction in motion,

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1 and radiographic findings, and as you would suspect,  
2 the majority of these patients would fall into the  
3 higher Wilkes stages, which is consistent with these  
4 patients should exhaust all nonsurgical therapy,  
5 clearly, before ever proceeding to a total joint  
6 replacement.

7 This, again, I think tempers some of the  
8 results of the study, and they're very similar in  
9 the total and the cohort, the number of prior  
10 studies, and you can see they can range anywhere  
11 from zero to 29.

12 Zero would be a traumatic fracture where  
13 there's an irreparable fracture, and you would go  
14 right to a prosthesis. The 29 would be an  
15 unfortunate patient who underwent a lot of previous  
16 procedures.

17 The three major baseline characteristics  
18 we followed were, again, jaw pain intensity,  
19 interference with eating, and these two were on a  
20 visual analogue scale of zero to ten, where zero was  
21 the best and in pain, ten was the worst pain  
22 imaginable, and on the diet scale ten was liquids

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1       only. And the maximal interincisal opening, these  
2       are baseline findings between total and cohort,  
3       which are relatively similar, but they started  
4       around 19 to 20.

5                   And, again, as we mentioned, we feel  
6       it's a reasonable goal to get probably 30 to 33  
7       millimeter opening in the multiply operated patient.

8                   The diagnoses are multiple because  
9       obviously these don't add up to 100, but if we look  
10      at the two most common, they are osteoarthritis and  
11      ankylosis, and then we had a separate traumatic  
12      arthritis when there was an identifiable event that  
13      began these symptoms.

14                   In cement usage, as we mentioned early  
15      on, when we were using PMMA cement, of the total  
16      cases 38 were cemented and 142 are uncemented, and  
17      the last cemented case was 1998.

18                   In the mandibular component, as we  
19      discussed the different designs, the narrow design,  
20      we've used 197. The standard, which is the broader  
21      that gives you just more options for screw  
22      placement, and in two patients who had documented

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1 nickel sensitivity, and these patients are actually  
2 tested with nickel patch testing by a dermatologist  
3 prior, and then in both cases we got FDA approval to  
4 make the mandibular component out of titanium. As  
5 you recall, the screws are the titanium alloy.

6 This is the follow-up. If you look at  
7 the landmarks of follow-up, and Mary is going to go  
8 through the statistics from this point on, and then  
9 I'm going to discuss the adverse events at the end.

10 MS. VERSTYNEN: Patient accountability.  
11 This shows once again while the study went from one  
12 month to three-year follow-up, I also did include  
13 the four and five-year follow-up because we did make  
14 an effort to follow the patients past the three-year  
15 study time point.

16 As you can see, the bottom line and the  
17 most important thing on this slide is the percent  
18 follow-up from the one month to the three years, and  
19 at all time points we were at greater than 80  
20 percent.

21 The only loss to follow-ups that were  
22 calculated on this slide were deaths and total joint

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1 removals, but obviously people do not return for  
2 visits. People move; people are lost. So that  
3 accounts for why we would have some patients  
4 theoretically due at one month of 180 when we  
5 actually saw 170 patients.

6 I mean, the patients schedule, and they  
7 don't come back. And Dr. Quinn and Dr. Sinn can  
8 probably talk a lot more in detail why patients  
9 don't come back for follow-up.

10 The clinical findings, the primary  
11 effort to see endpoints in both T tests and repeated  
12 measures analysis. They showed a significant change  
13 from baseline to three years, and remember this  
14 study was designed to show improvement.

15 This slide shows perfectly how well the  
16 three groups that were analyzed compare, and if you  
17 look to see, they follow the exact same pattern from  
18 baseline to three years throughout the course of the  
19 study, with the baseline mean being at eight and the  
20 error bars are put in for just the standard  
21 deviation only just so it wouldn't complicate the  
22 slide.

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1                   But you can definitely see even at the  
2 one month time frame there was a tremendous amount  
3 of improvement in jaw pain, continued down at three  
4 months, and pretty much plateaued from the six-month  
5 to the three-year time frame.

6                   This was also seen very similar on the  
7 interference with eating. Remember these were all  
8 in the ten centimeter VAS scale where, once again  
9 baseline mean for all three groups was approximately  
10 eight centimeters, dropped drastically at one month,  
11 continued going down at three months, a little  
12 decrease still at six months, and then pretty much  
13 plateaued out to three years, which pretty much  
14 seemed to be somewhat predictive then.

15                   By the three and the six month mark, the  
16 patients had pretty much plateaued to what they were  
17 at the end of the study.

18                   The same thing for the MIO. They  
19 started off with approximately a 19 millimeter  
20 opening and went up drastically at one month and at  
21 three months and was continuing up, and this pretty  
22 much looked like it plateaued then out to the three-

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1 year mark.

2 So you can definitely see that there was  
3 a tremendous amount of improvement seen in the  
4 primary efficacy endpoints.

5 Also, to show this even in another  
6 visual way, once again, this was the baseline  
7 reading. We wanted to see the difference between  
8 baseline and each of the time frames, and this slide  
9 actually incorporates both primary and the secondary  
10 efficacy endpoints.

11 We can drastically see the difference  
12 between baseline and three years, which was the  
13 primary endpoint, and then each of the secondary  
14 endpoints then are shown at the one month and all of  
15 the follow-ups.

16 And you can definitely see there was a  
17 tremendous amount of significance in improvement for  
18 jaw pain, and you can also see the exact same thing  
19 then for the interference with eating and the same  
20 thing for the MIO.

21 Once again, this was just to visually  
22 show you what the baseline reading was and then to

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1 actually show the improvement over time

2 Secondary efficacy endpoints also  
3 included the degree of patient satisfaction.

4 Ninety-three percent or more of the patients were  
5 satisfied or better at all time frames, and that  
6 includes out to the six years, and for the hindsight  
7 question, whether patient would choose to have a  
8 surgery, 91 percent or more said yes at all of the  
9 time frames.

10 This slide is just to show you that with  
11 the additional efficacy data that was collected for  
12 collusion, anterior open bit, and cross bite, there  
13 was also an improvement seen from baseline to three  
14 hours in these three assessments.

15 I will hand it over now to Dr. Quinn to  
16 complete the clinical presentation, and he will  
17 start off with safety findings.

18 DR. QUINN: Thanks.

19 As we mentioned, we reported adverse  
20 events. You'll see, I think, we over reported them.  
21 We're very conservative with that.

22 There weren't any mechanical failures.

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1 There were permanent device loss, and we'll go over  
2 all of them. And the permanent device removals  
3 occurred in 11 cases and 12 joints.

4 Now, we defined "permanent" that it was  
5 removed. In three of these the fossas have been  
6 replaced. One of them is as long as two and a half  
7 years later, but we are still listing these as  
8 permanent device removals because the other  
9 definition we used was same day revision.

10 I don't want it to be confusing, but  
11 same day revision is where we went in, removed a  
12 prosthesis, for example, for heterotopic bone,  
13 removed the heterotopic bone and replaced the  
14 prosthesis. And that occurred in five joints, four  
15 cases where we had to remove the heterotopic bone,  
16 and in one case where there was a dislocation of the  
17 condyle, and we went in and replaced it with a 50  
18 millimeter to a 45 millimeter to reseal it.

19 This is the total number of adverse  
20 events which are not requiring device removal, and  
21 again, I do think that we made an effort to over  
22 report. I'll give you some examples of these.

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1           Excision of tissue included both removal  
2           o heterotopic bone and also removal of incisional  
3           neuroma because a lot of these patients especially  
4           who have had multiple incisions have incisional pain  
5           that can occur in any type of incision, and some of  
6           them postoperatively were taken back to remove the  
7           scar in an attempt to remove an incisional neuroma.

8           We reported any time when there was a  
9           motor vehicle accident even if there was no direct  
10          facial trauma because we did see that it did  
11          correlate with an increase in symptoms even if there  
12          was no direct maxillofacial trauma.

13          Coronoidectomy, I think there's some  
14          experiential wisdom here. In the beginning of the  
15          case, we probably did not remove coronoids as much.  
16          We were recommending in the multiply operated  
17          patient at the time of the original surgery that the  
18          coronoids were removed.

19          We did have to go back and remove  
20          coronoids. That's from an intraoral approach, and  
21          it does avoid contaminating the implant.

22          Again, these are all adverse events that

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1 did not require a device removal, and as I  
2 mentioned, we had no mechanical failures. This does  
3 come out to a 30 percent AE incidence, and 55  
4 patients at the 180 cases, but it was six cases or  
5 3.3 percent that had AEs that were device related  
6 And, again, as I mentioned before, the number that  
7 had the permanent removals.

8           Given the patient population where I  
9 think the term "reasonable expectations" comes in,  
10 these patients do have, especially in the multiply  
11 operated patient, preexisting conditions, nerve pain  
12 secondary to multiple surgery which will not be  
13 addressed by a prosthesis, and some of these  
14 patients are chronic pain patients as well.

15           Looking at the surgical site, most of  
16 the wounds healed within the first three months  
17 postoperatively. The ones where we had wound  
18 infections I showed an example of where we had  
19 device removal.

20           Radiographic assessment was done at all  
21 of the landmarks, and we used the baseline of the  
22 day after surgery where a PA cephalometric X-ray was

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1 taken, a lateral cephalometric X-ray, a Panorex, and  
2 they were compared at the other landmarks for change  
3 in position of the fossa or the condyle.

4 Most of the radiographic changes were  
5 associated with the heterotopic bone or in the  
6 joints that were removed.

7 There was a subgroup analysis done for  
8 a covariate analysis and multivariate analysis, and  
9 all the detail of that is in your handout.

10 What did occur from that analysis was  
11 that there were some statistically significant  
12 differences in the variable analysis, but none of  
13 them were clinically significant.

14 If you looked at groups where one has a  
15 three centimeter improvement in opening, the other  
16 subgroup had a four centimeter. They were, again,  
17 statistically significant, but all of the groups did  
18 well enough, and so they weren't clinically  
19 significant.

20 In summary then we had a success rate by  
21 the definition that we went over in the beginning of  
22 the presentation in the cohort on imputed group, the

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1 97.8 percent, and the cohort imputed group of 94.9,  
2 and then the total study group of 95.1, and we had  
3 greater than 60 percent of the cases met the patient  
4 success criteria, and as we said, those criteria  
5 were a centimeter improvement in pain scale, a  
6 centimeter improvement in diet scale, and ten  
7 percent improvement in the MIO.

8 The study conclusions is that we feel  
9 this is a safe and efficacious implant. There was a  
10 significant improvement with a significant P value  
11 seen in the primary and secondary efficacy  
12 endpoints.

13 Patient satisfaction was what we  
14 reported, approximately 91 percent, and the rate of  
15 AEs even including device removal was an acceptable  
16 rate considering the patient population, and we had  
17 no unanticipated adverse events.

18 In summary, we think this prospective  
19 study has shown that the Water Lorenz total TMJ  
20 replacement system is safe and effective for the  
21 variety of diagnoses that we've shown.

22 Thank you.

1 CHAIRMAN HEFFEZ: Thank you very much.

2 I would like now to proceed to any  
3 questions that the panel may have. Any panel member  
4 who wishes to ask a question, please signal to me  
5 and identify your name prior to the question.

6 DR. PATTERS: Mark Patters.

7 A question for Dr. Quinn. Could you  
8 discuss the patients lost to follow-up? Because  
9 there's always a concern that that represents a  
10 population that's dissatisfied rather than that is  
11 consistent with the total population.

12 DR. QUINN: I'll separate the amount of  
13 patients who are lost to follow-up. There were  
14 three deaths in the study, and the three deaths were  
15 one was a patient who had a temporal lobe tumor who  
16 died of a recurrent brain tumor.

17 The second patient died from a fulminant  
18 hepatitic reaction to Toradol three weeks after  
19 surgery.

20 And the third patient died from  
21 complications of back surgery. So there were three  
22 loss to follow-up from death.

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1                   Of the other patients that were lose to  
2 follow-up, the majority of the problem is distance.  
3 We do a zip code analysis at the University of  
4 Pennsylvania, and based on this study I now have the  
5 widest zip code analysis patient referral base. So  
6 most of the patients, it's distance.

7                   And my impression is that if they're  
8 doing well they don't want to get on a plane and fly  
9 back from Oregon for a 20 minute appointment in  
10 Philadelphia. That is a problem.

11                   So my impression is that the percent  
12 follow-up, given this patient population, is  
13 laudable, but you're right. It is a concern, and  
14 the problem is coaxing patients back in. We have no  
15 problem getting patients back in who have  
16 complaints.

17                   DR. BURTON: Richard Burton.

18                   This question, Dr. Quinn, deals with  
19 your indications and your patient population. The  
20 first one is that one of your indications and one of  
21 your exclusion criteria was that they would be  
22 skeletally mature.

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1                   But then looking at the demographics,  
2                   that shows at least one male that was 12, and then a  
3                   13 year old female, and most of us would obviously  
4                   not consider those to be skeletally mature. So I  
5                   guess my question is why. There was no indication  
6                   why they were included.

7                   DR. QUINN: The 13 year old female was  
8                   by hand wrist filmed, finished skeletal growth.

9                   DR. BURTON: Okay.

10                  DR. QUINN: And she's the patient I  
11                  showed, the young Afro-American female with the  
12                  keloids and the ankylosis.

13                  DR. BURTON: Okay.

14                  DR. QUINN: That is her. The 12 year  
15                  old patient, the patient of Dr. Sinn's -- and, Doug,  
16                  if you want to comment -- that patient was approved  
17                  by the FDA as an exclusions even given his age.

18                  DR. BURTON: Well, they were an  
19                  exception to that.

20                  Also, what is your intent in the  
21                  section? You talk about one of the indications is  
22                  developmental abnormalities. That's sort of a broad

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1 term, but what you really intend by that statement.

2 DR. QUINN: Development abnormalities,  
3 we may have a congenital absence of the whole --  
4 rami are kind of like hemifacial microsomia or  
5 Golden-Harr syndrome.

6 Obviously, the procedure of choice in a  
7 developmental abnormality prior to skeletal  
8 maturation in our hands is still a costocondyle  
9 graft, but developmental abnormalities after  
10 skeletal maturation could be addressed with the  
11 prosthesis.

12 DR. BURTON: And lastly you had some  
13 individuals who were -- at least a couple that were  
14 Wilkes Class I and then a couple of IIs and IIIs.  
15 What were the other co-morbidities that usually  
16 would indicate that they would be included? Was  
17 that a fracture patient or something along that  
18 line?

19 DR. QUINN: Either fractures or a tumor  
20 where the amount of bone removed in the tumor  
21 excision would require either a prosthesis or an  
22 autogenous joint.

1 DR. BURTON: Okay. Thank you.

2 DR. SUZUKI: Jon Suzuki.

3 This is a question for Dr. Quinn.

4 Apparently the condylectomies that are  
5 required to place this device are somewhat radical,  
6 and an additional part of the mandible is taken off.  
7 Given the morbidity, what options does a surgeon  
8 have for reconstitution or replacement of it should  
9 this fail?

10 DR. QUINN: That's a good question. You  
11 do have to remove more of the condyle approximately  
12 three millimeters below the sigmoid notch to  
13 accommodate the thickness of the glenoid fossa.  
14 That is an irreversible step, as you point out.

15 And I'll phrase it in two questions.  
16 you always have the option in a failed prosthesis to  
17 go back to an autogenous graft. I think there's  
18 some complications there because the more these  
19 patients are operated on, the more scarred the bed  
20 is and the more complications you will get with  
21 autogenous grafts.

22 The other option, and I should mention

1 this, is that this is a stock prosthesis, and it  
2 comes in three different sizes, and humans always  
3 don't come in three different sizes. You always  
4 have the option at the time of surgery, the stock  
5 prosthesis once the surgeon is in the joint. It  
6 doesn't fit, is inappropriate. you stop the  
7 procedure, put the patient in IMF. Do a 3D CT scan  
8 in the hospital, and you can proceed with a well  
9 designed custom joint like the TMJ Concepts.

10 And we do encourage surgeons that that  
11 is an option if they run into anatomical problems.  
12 Is that addressing your question?

13 DR. SUZUKI: Yes. Thank you.

14 DR. COCHRAN: David Cochran.

15 I had a question about the timing of  
16 your adverse events. When those occurred, it looked  
17 like from some of the information they occurred  
18 around the six month time point. Would you  
19 elaborate on that a little bit?

20 DR. QUINN: The timing of when the  
21 adverse events occurred?

22 DR. COCHRAN: Yes.

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1 DR. QUINN: I think they occurred  
2 throughout the entire study. Maybe I'm  
3 misinterpreting the question.

4 DR. COCHRAN: Yeah, it looked like just  
5 from what was listed in the material we had, it  
6 looked like they were occurring from four to ten  
7 months. The main ones were listed. I think there  
8 was one lost later on, but normally four to ten  
9 months seemed to be when most of the adverse events  
10 occurred.

11 DR. QUINN: Well, for the major adverse  
12 events, infection and heterotopic bone, that would  
13 be the time frame it would occur in. I'd ask either  
14 Mary or Joe Canner if you want to discuss the  
15 statistics. Maybe I can't answer the question as  
16 well.

17 MS. VERSTYNEN: Yeah. Mary Verstynen.  
18 I believe that the adverse events  
19 occurred throughout the study, but I guess if you go  
20 back and look and remember the patient  
21 accountability, the majority of whole joint  
22 revisions were done between the six month and the

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1 one and a half year time point. It seemed to be at  
2 that point is when the patients went back for the  
3 total joint.

4 So I don't know. Does that answer it  
5 somewhat?

6 But literally the rest of the adverse  
7 events occurred throughout the study.

8 CHAIRMAN HEFFEZ: Dr. Rekow.

9 DR. REKOW: Diane Rekow.

10 I have a question for Dr. Quinn, and  
11 then I have another question for Shawn, please.

12 Dr. Quinn, can you talk about and have  
13 you done any correlation -- let me start again.

14 My impression as I read the materials  
15 was that you used the bone cement with a post early  
16 on, and then you started removing the post and not  
17 using the cement. Then that evolved into a new  
18 design. Is there any correlation between the  
19 adverse effects and the use of cement or non-use of  
20 cement and the design of the fossa?

21 DR. QUINN: I believe that was one of  
22 the subgroup analysis, and I don't think there was a

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1 statistical significant difference because as you  
2 mentioned, we stopped in 1998.

3 Of the patients who were out -- Mary,  
4 can you help me with the numbers? -- of the patients  
5 who were out three years, of the breakdown, I think  
6 it's 38 and six.

7 MS. VERSTYNEN: Well, there were 38  
8 cemented cases, and they were obviously done early  
9 on in the study. So there were 31 of Dr. Quinn's  
10 and there were seven of Dr. Sinn's. So these, this  
11 grouping of patients, were their first patients that  
12 were enrolled into the study.

13 Does that answer it or do you want --

14 DR. REKOW: And there's nothing  
15 different?

16 MS. VERSTYNEN: And the thing is I guess  
17 you could kind of go back and look at the key  
18 numbers. I mean, with the listing of adverse  
19 events, they probably fell within the first 40 key  
20 numbers. I don't know that those cases had more  
21 adverse events than the rest of the patients.

22 DR. REKOW: Have you -- have you --

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1 MS. VERSTYNEN: But we haven't actually  
2 looked at the 38 and correlated it back to the  
3 numbers of adverse events.

4 DR. REKOW: Okay. That was really my  
5 question.

6 MS. VERSTYNEN: Actually it was a good  
7 point. The 38 cases were all in the cohort group,  
8 but once again, we didn't list adverse events by  
9 cohort. We just listed them by the total of 180  
10 cases

11 DR. REKOW: Okay, and then, Shawn Roman,  
12 you provided some nice information about averages  
13 for your mechanical testing, but I didn't see any  
14 ranges or standard deviations. Can you give us some  
15 sense of how closely the five joints performed  
16 relative to each other?

17 MR. ROMAN: With respect to the?

18 DR. REKOW: Well, the fatigue testing  
19 and your screw pull-out tests and those sorts of  
20 things. The averages are wonderful, but you could  
21 have interesting results with nice averages.

22 MR. ROMAN: Right. I don't have those

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1 numbers off the top of my head, but I can get those  
2 from the test reports if you'd like me to do that.

3 DR. REKOW: I think at some point it  
4 would be useful to see those.

5 MR. ROMAN: Okay.

6 DR. REKOW: Thanks.

7 CHAIRMAN HEFFEZ: We can entertain  
8 another question.

9 MR. ROMAN: Just pointing out the fact  
10 that on fatigue testing there is no variability.  
11 The fatigue testing just stops at the --

12 DR. REKOW: Right, right, but for the  
13 bending tests and for the pull-out tests?

14 MR. ROMAN: Sure. How would you like to  
15 work this? I can get the numbers and then come back  
16 to the podium and answer that question for you?

17 CHAIRMAN HEFFEZ: Yes.

18 MR. ROMAN: Okay.

19 CHAIRMAN HEFFEZ: We'll proceed.

20 Ms. Helms.

21 MS. HELMS: Thank you.

22 Elizabeth Helms.

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1 I have several questions around the  
2 function of the mandible after implantation with the  
3 screws. The screws loosen up. Do you have to go  
4 back in? Has there been a change in the body of  
5 these patients?

6 If you could describe how many patients  
7 have had screws that have loosened up. What happens  
8 to the body if any of this is reabsorbed?

9 And for the nickel testing, do you do  
10 any type of testing for nickel allergies prior to  
11 implantation?

12 DR. QUINN: Maybe I'll answer them in  
13 reverse.

14 MS. HELMS: All right.

15 DR. QUINN: Nickel testing, if a patient  
16 tells us they have nickel sensitivity, and most  
17 patients who have nickel sensitivity, it's a jewelry  
18 issue because of the preponderance of nickel in  
19 jewelry, and we have small samples of the materials.

20 The polyethylene and the cobalt chrome  
21 from the company that we send to a dermatologist,  
22 have the patient seen by the dermatologist, and

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1 they're patch tested. I'm not sure there's any  
2 other way other than taking a history and doing a  
3 patch test.

4 If there's a reaction to the patch  
5 testing, then we have gotten permission to use  
6 titanium in the ramal component as well as the  
7 screws.

8 We haven't had any screws loose in  
9 there. I have had screws loose in implants that  
10 we've used in the past. Fortunately we've had no  
11 device failures.

12 The question about wear, I think there  
13 is wear in all prosthetic implants. The implants  
14 that we have gone back into for infection or for  
15 heterotopic mode, we've taken tissue samples. One  
16 of the samples came out with a foreign body  
17 reaction. When it was put under polarized light,  
18 the official diagnosis that it was corn starch  
19 because it polarizes in a very particular way was  
20 probably from a glove.

21 So we haven't seen any evidence of  
22 foreign body reaction yet.

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1 CHAIRMAN HEFFEZ: Dr. Hewlett, you had a  
2 question?

3 DR. HEWLETT: Yes. Edmond Hewlett for  
4 Dr. Quinn

5 I noticed in your statistical analysis  
6 or actually in your demographic data collection that  
7 patient ethnicity was not one of your demographic  
8 variables.

9 A two-part question: have you  
10 considered at any point or make a specific decision  
11 not to include that?

12 And the second part is that did you  
13 nonetheless based on just your empirical experience  
14 in the study notice any propensity for specific  
15 adverse effects, such as heterotopic bone or  
16 ankylosis with respect to any particular ethnic  
17 groups?

18 DR. QUINN: Well, the numbers wouldn't  
19 be high enough. Anecdotally, I think in my patient  
20 population and only in the females, there were three  
21 African American females. Only one of them have  
22 this serious heterotopic bone. I do think there is

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1 a higher propensity in African Americans in general  
2 for keloids. I don't know whether that translates  
3 into heterotopic bone.

4 My experience with heterotopic bone is  
5 it gets worse as the number of operations gets. I  
6 think the actual surgery in and of itself is the  
7 trigger for further and further scarring in  
8 heterotopic bone, but I'm not sure I'm an expert in  
9 it beyond that.

10 As you said, we did not follow up  
11 density. We followed gender alone, and gender is  
12 the striking differential in all of these TMJ  
13 studies, as you well know.

14 CHAIRMAN HEFFEZ: Dr. Bertrand.

15 DR. BERTRAND: Peter Bertrand.

16 For Dr. Quinn, I seem to remember  
17 reading that ten sites were okayed to participate in  
18 this study. Yet almost all of the surgeries are  
19 done by you and Dr. Sinn. Can you shed some light  
20 on why predominantly just you and not more sites?

21 DR. QUINN: One of it is a temporal  
22 issue. Since we started this process in 1992, I

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1 think we were somewhat geared up for that patient  
2 population.

3 The other is this is exclusive what I  
4 do. I only do TMJ surgery. My five partners won't  
5 do any of it, and we have a large center.

6 We also have, as you know, a TMJ clinic  
7 that sees a huge number, and our surgery rate is  
8 about six percent out of 100. So we tend to draw  
9 from a larger population.

10 Dr. Sinn is in a similar position at  
11 Southwest Texas. He came out in 1998. I think the  
12 other investigators, I think there's two sides to  
13 that. There are investigators who have given us the  
14 impression that they have lots of patients and they  
15 didn't materialize, and they came in later in the  
16 course, as in the last year or so we have been  
17 holding off and not doing more IDEs and IRBs because  
18 they're so labor intensive to do for somebody who  
19 may do two or three surgeries.

20 DR. BERTRAND: I understand. The second  
21 question, there seems to be an evolutionary process  
22 in the design of the standard mandibular component.

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1 Do you anticipate any more design changes for the  
2 product?

3 DR. QUINN: No. And it is. It's  
4 experiential wisdom. I think as you go on and you  
5 run into joints where you don't have adequate bone,  
6 where a bigger footplate would give you more  
7 options, that clearly was one.

8 The other one was the medial lateral  
9 issue because, again, this is a stock prosthesis,  
10 and it does take some experience on the surgeon's  
11 hands to fit this. But if the fossa is fit first  
12 and there is some variability between where the  
13 condyle sits under that fossa, you have some leeway  
14 in terms of encountering bone, but we wanted to have  
15 the option to have the same offset in a lateral  
16 direction as the medial direction, if you did get  
17 one of them where you could.

18 It's relatively easy if the prosthesis  
19 is too lateral to do bony contouring to get it in.  
20 If it starts off to medial, you would have to do a  
21 lot of shimming with bone, which we don't want to  
22 do. So we made the other offset size.

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1 I don't anticipate any more at this  
2 time, but I'm not sure I could sign an affidavit to  
3 that.

4 DR. BERTRAND: I understand. There  
5 seems also to be an experience level with how  
6 quickly and efficaciously you can do this surgery.  
7 Do you anticipate, with all of your experience and  
8 somebody new, anticipating using these devices  
9 having some type of mentorship program?

10 DR. QUINN: Clearly. I think without  
11 training and education this is very experience  
12 based. In fact, I think one of the things that did  
13 occur during the course of the surgery is it's a  
14 much faster procedure when you have all of the  
15 instruments that are designed specifically for it,  
16 the burs, the retractors. Our average time per side  
17 now is about two hours and 20 minutes. In the  
18 beginning it was over four.

19 DR. BERTRAND: Thank you.

20 DR. BURTON: Richard Burton, again, for  
21 Dr. Quinn.

22 I'd like to continue with what Dr.

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1 Bertrand asked because I have concerns which you  
2 explained regarding the site and the question of  
3 site bias, but my concern looking through your  
4 surgeon materials is the fact that they're very  
5 good, but again don't obviously convey some of the  
6 complexity of this.

7           And whether or not you looked at whether  
8 your complication rate -- and when I went through  
9 the adverse events, it appeared that there was not a  
10 -- that they spread throughout the study, but there  
11 were certainly, it seemed, a slightly higher rate.  
12 Did you look at that earlier in the early patient  
13 groups?

14           And again, whether there was a learning  
15 curve, obviously you said your own surgical time  
16 improved, which would be a normal expectation, but  
17 again, how you may address the surgeon education  
18 issue when this was released.

19           Because, again, you know, currently  
20 virtually all of these have been done by yourself  
21 and Dr. Sinn, and again, both of you are, I think,  
22 well known and well experienced, but when his

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1 product is released and given out to hands with much  
2 less experience, and again, none with this  
3 particular product and how you intend to address  
4 that.

5 And then one other question that sort of  
6 goes in with that if you've addressed many times  
7 that one of the most common problems you had was  
8 heterotrophic bone formation, again, in multiply  
9 operated joints. You made a comment earlier about  
10 the use of radiation in one of the patients.

11 Are you advocating that, and if so, how  
12 many patients did -- I didn't see anything where it  
13 said how many patients had received radiation in  
14 conjunction with their overall treatment.

15 DR. QUINN: Okay. Well, the only one  
16 patient received it, and it was actually three weeks  
17 ago after this data was closed.

18 I only have experience with three  
19 patients, and our experience is really drawn from  
20 the orthopedic literature because there isn't a lot  
21 in our literature how you deal with heterotopic  
22 bone, except for EDTA chelating agents which don't

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1 seem to be very effective, and indomethacin, which  
2 we have also tried.

3 A dose of 100 rads, given 200 rads per  
4 day, seems to be efficacious, but our n is too small  
5 for me to make any statement.

6 To go to your original statement about  
7 adverse events, I do think there are some correlates  
8 that, in general, in the maxillofacial literature,  
9 you can look at infection rates, and they do  
10 correlate in general in orthognathic surgery, where  
11 it is published more, the longer that site is open,  
12 the higher the infection rate. I think there is  
13 some correlation to time of surgery.

14 It wasn't part of our analysis, but I do  
15 think if you take a two-hour operation and take ten  
16 hours to do it, you're probably going to increase  
17 your rate of infection. That's anecdotal. I have  
18 no data to support that.

19 To the training issue, I couldn't agree  
20 with you more. I think if there is any silver  
21 lining to the Proplast debacle, that as you well  
22 know, the majority of oral maxillofacial surgeons in

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1 practice have decided TMJ surgery is not something  
2 they're wildly enthusiastic about. I somewhat hope  
3 it stays that way.

4 These are done at centers by people who  
5 do at least a modicum of surgery because experience  
6 is part of it.

7 In terms of the training, currently the  
8 plan is that Dr. Sinn or I would do a surgery with  
9 anyone contemplating doing this, and they would have  
10 to take a formal course that goes over all of the  
11 testing, the designs, the biomechanical and surgical  
12 technique.

13 We've produced a video that is in  
14 preparation. Beyond that I would be open to  
15 suggestions because I do think it's an important  
16 point.

17 DR. BURTON: Thank you.

18 DR. ANSETH: I had a question for Mr.  
19 Roman.

20 CHAIRMAN HEFFEZ: This is Kristi Anseth.

21 DR. ANSETH: My name is Kristi Anseth.

22 And my question relates to some of the

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1 wear properties of the components that you were  
2 testing, and I was wondering if you could comment  
3 more specifically on that.

4 And then also, with some of the changes  
5 in using the cement and noncemented, if you could  
6 comment on the differences that might exist both in  
7 fatigue and wear.

8 MR. ROMAN: Okay. The materials used  
9 for both the fossa component and the mandibular  
10 component are materials that we've had a wide range  
11 of experience with previous to this design in  
12 orthopedic applications.

13 The wear characteristics were looked at  
14 on all of the fatigue testing. The articular  
15 surfaces of the fossa components were looked at, and  
16 there was no sign of wear after the ten million  
17 cycles in the fatigue testing.

18 Does that answer your first question?

19 And the second question, could you  
20 repeat?

21 DR. ANSETH: So you also presented data  
22 on even the cemented version of the fossa.

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1 MR. ROMAN: Right.

2 DR. ANSETH: And I was curious what you  
3 think of differences when you have no cement.

4 MR. ROMAN: Okay. We're actually trying  
5 to -- well, the cement that -- first of all, the  
6 bone cement was never intended to be used as a means  
7 for fixating the fossa component. It was just meant  
8 to fill voids between the fossa component and the  
9 glenoid fossa component. The sole means of fixation  
10 would be the fossa screws.

11 But we are currently doing some fatigue  
12 testing to look at the difference between the fossa  
13 components that had the post manually removed as  
14 compared to fossa components that were machined  
15 without the post, and in both of those cases, we're  
16 redoing that fatigue testing without using bone  
17 cement because that is how they would be implanted.

18 And we're testing five devices. Four of  
19 the devices are complete now, and they have all made  
20 it out to ten million cycles with no failures of the  
21 devices.

22 DR. REKOW: Can I ask a follow-up?

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1                   Diane Rekow. Can I ask a follow-up  
2 question?

3                   When you're doing that fatigue testing,  
4 what do you have as your supporting system under the  
5 fossa? Does it have a modulus that's similar to the  
6 bone or is it a steel or you know?

7                   MR. ROMAN: Yeah, it's aluminum. So it  
8 would be stiffer than the bone. That would be in  
9 vivo.

10                  DR. REKOW: Okay.

11                  MR. ROMAN: Did you want me to follow up  
12 now with the question I was asked earlier on the  
13 standard deviations or do you want to --

14                  CHAIRMAN HEFFEZ: Sure, yes. Go ahead.

15                  MR. ROMAN: I was able to find the  
16 standard deviations on two of the four tests that  
17 weren't the T testing. On the fossa screw pull-  
18 through testing, there was a standard deviation --  
19 there was an average of 79.8 pounds with a standard  
20 deviation of 2.5 pounds.

21                  On the pull-out strength of the 2.7  
22 millimeter self-tapping screws, it was an average of

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1 373 pounds with a standard deviation of 68.8 pounds,  
2 and it's a slightly larger standard deviation that  
3 was discussed, and it's probably the result of using  
4 bovine cortical bone for the testing.

5 There was a concern over the standard  
6 deviation there because the loading was so high, and  
7 the other two tests that were performed, the static  
8 testing of the mandibular component and the static  
9 testing of the fossa component, there were no  
10 standard deviations listed in the old test reports.

11 DR. REKOW: Do you have the ranges?

12 MR. ROMAN: Actually there's -- that  
13 data is not listed in the testing report. I think  
14 that the reason for that was because of the mode of  
15 failure that was seen. It was anticipated that the  
16 mandibular component would fracture at the flange.  
17 Actually the mode of failure occurred in two  
18 different stages with the mandibular component.

19 The first stage actually involved  
20 splitting of the bone, the tibial bone from the  
21 first screw up to the top surface of the bone, and  
22 then once that splitting occurred, then the bending

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1 of the mandibular component occurred.

2 So then on the fossa components, again,  
3 the anticipated mode of failure was fracture of the  
4 fossa flange, but when the fossa flange bent with no  
5 breaking, that was deemed acceptable solely because  
6 they would have the support of the temporal bone in  
7 vivo.

8 So were those numbers that were reported  
9 then the minimums for the set that were tested or  
10 were they the average? Do you -- I know that this  
11 is probably old data, and you may not have the  
12 answers immediately available.

13 MR. ROMAN: I don't, but they are  
14 discussed as the average in the test reports.

15 DR. REKOW: Okay. Thanks.

16 MR. ROMAN: But as long as we're  
17 catching up on questions, we did have some  
18 additional information for adverse effects that can  
19 be answered by our contract statistician.

20 MR. CANNER: My name is Joe Canner.  
21 I'm a statistical consultant with Hogan & Hartson in  
22 Washington, and I have financial interest in Biomet

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1 or Lorenz.

2 There was a question asked about adverse  
3 events after cement or noncement, and we did do that  
4 analysis, but I would strongly encourage caution  
5 with respect to the interpretation of it, although  
6 the results are fine. There was no statistically  
7 differences.

8 But any time those kinds of issues come  
9 up, keep in mind as was mentioned that the cemented  
10 cases were the first 38 cases and the noncemented  
11 were following that. So any patient selection  
12 issues, any learning curve issues will by nature  
13 complicate that analysis.

14 It does appear that, as was mentioned  
15 before, most of the removals -- and I'm sorry. I  
16 meant to say that I'm talking specifically about  
17 removals here because those are the adverse events  
18 that probably are most relevant to the device. Most  
19 of them do appear to occur in the first 12 months  
20 and even in the noncemented cases, all of the  
21 removals were in the first 12 months, and even  
22 though there were a number of patients who were in

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1 that group who were followed out to two and three  
2 years,

3 So to recap, there was no statistically  
4 significant difference between cemented and  
5 noncemented cases in the rate of removal, but again,  
6 it would be difficult to make too much of that one  
7 way or the other because of changes over time and  
8 patient population and in surgeon experience.

9 CHAIRMAN HEFFEZ: Dr. Li.

10 DR. LI: Steve Li, either for Dr. Quinn  
11 or Mr. Roman.

12 I'd like to revisit the polyethylene  
13 wear issue. As you've mentioned the TMJ is kind of  
14 a corollary to the total hip and total knee system,  
15 and in this case it's a more conforming joint, so  
16 more similar to a total hip than a total knee, and  
17 yet your stresses are about two to three times that  
18 of a total hip.

19 So my question is: do you see signs of  
20 polyethylene wear either in radiographs or on your  
21 explants or in tissue analysis? And if you don't,  
22 why would that be?

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1 DR. QUINN I'll ask Shawn to answer  
2 some of the general questions about polyethylene  
3 wear because I'm not the expert, but I think if you  
4 -- first of all, there's on real consensus as what  
5 are the stresses place on not only the prosthetic  
6 joint, but on the human joint.

7 You could start an argument as to what  
8 is the pounds per square inch under normal  
9 mastication. We used 145 pounds as the upper limit,  
10 which I think is a good estimate, but in this  
11 patient population in the multiply operated joints,  
12 there are studies that have viewed something as  
13 crude as a dynamometer in multiply operated. Their  
14 masticatory forces are much less.

15 So I think although by definition this  
16 is a patient population who has already had multiple  
17 procedures, I wouldn't expect that they could even  
18 achieve the normal range of stresses.

19 The other is I'm not sure I correlate  
20 directly to a conforming hip joint where there's  
21 confluence because there is some aberrant motion in  
22 this joint that is not directly related to a hip.

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1 DR. LI: But that would tend to increase  
2 the wear though.

3 MR. ROMAN: Right.

4 DR. LI: So my question is: do you see  
5 clinical signs of wear, either radiographically in  
6 the analysis of removed components or in surrounding  
7 tissues when you've gone in to do procedures?

8 DR. QUINN: Excuse me. Radiographically  
9 we haven't. Of the joints I opened for other  
10 reasons, heterotopic bone and infection, when we did  
11 tissue samples, the only foreign body, as I  
12 mentioned, was what they came back and said was more  
13 likely to be corn starch and not polymeric debris  
14 so --

15 DR. LI: Were those just -- I'm sorry --  
16 were those just optical micrographs, with your eyes?  
17 It wasn't electron microscopes?

18 DR. QUINN: These were histologic EMN  
19 and then they were under polarized, but looking for  
20 foreign bodies.

21 DR. LI: Right. So typically in the  
22 larger joints the particles that form osteolysis are

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below the levels of visible observation. So if you can actually see it with your eyes, they're too big to cause osteolysis. So unless you do some tissue analysis to look for these submicron particles, there could be millions in there, and you'll never see them just by looking with a histological sample.

So have you looked at anything other than histological samples?

DR. QUINN: No, we haven't, and I'll ask Shawn if we have data on the wear of this particular high molecular polyethylene, ArCom, which I think there is statistics on or Ken Beres might be able to answer that for us.

DR. BERES: I'm Ken Beres from Biomet.

I have a little bit more experience in the orthopedic realm. This joint is a cross between a total hip and a total knee. There is rotation of the joint similar to a total hip.

However, as Dr. Quinn said, there's also some translation, which would, again, move more towards a knee when you do have some sliding motion as well.

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1                   We thought about wear testing. We don't  
2                   have a good wear simulator for a TMJ. So we  
3                   couldn't do actual wear testing. There was no wear  
4                   noted in a fatigue test and no clinical signs of  
5                   wear noted.

6                   I don't have the data here. We could do  
7                   the stress analysis, the surface stress analysis on  
8                   the polyethylene. We could do that easily. I don't  
9                   think we have that data today.

10                  DR. LI: Well, the stress really isn't  
11                  that important because a total hip is about a  
12                  quarter, 15 percent to 25 percent of the yield  
13                  strength of the polyethylene, well below what you  
14                  reported for your Fugi film, but even at ten percent  
15                  of the yield stress, the rate of wear on total hip  
16                  is more than enough to cause the osteolysis over a  
17                  five to seven-year period.

18                  So even if the stresses were half of  
19                  what you said, that would still put you with a high  
20                  enough stress to cause significant polyethylene  
21                  wear.

22                  So I think a more accurate contact

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1 stress would be useful, but it doesn't get you away  
2 from the wear question.

3 DR. BERES: Well, you know, wear is a  
4 very good question. We're trying to avoid the  
5 question. I don't know. Besides the clinical data,  
6 I don't know we could do simulator testing. I'm not  
7 sure how we do that right now because the fixtures  
8 and the machines are just not available.

9 DR. LI: In your laboratory test, I  
10 would not guess looking at the schematic of the  
11 fatigue test that that actually would be a very good  
12 wear test, but you said you looked at the components  
13 and saw no wear. So is that just a visual "I see  
14 now wear" or did you actually weigh samples before  
15 and after or do something quantitative?

16 DR. BERES: No. No, there was no  
17 quantitative or no -- it was just simply visual.

18 DR. LI: Okay. Thank you.

19 DR. BERES: Now, on the other side, you  
20 mentioned the polyethylene is the ArCom  
21 polyethylene, which I believe in orthopedics is one  
22 of the more well known and gold standard, if you

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1 will. So we're using the same processing and all as  
2 with all the others.

3 DR. LI: Actually as you raise the  
4 issue, my understanding is ArCom actually can refer  
5 to several different products. For instance, I  
6 believe you have a product that you take the powder  
7 and you compression mold it into a bar, and then you  
8 machine the bar, and then you sterilize that in  
9 argon and call that ArCom.

10 There's also another product that you  
11 make where you take the powder and directly mold it  
12 into the final form with no machining and also call  
13 that ArCom, and they also may or may not use the  
14 same base polyethylene.

15 So when you say ArCom in this case,  
16 exactly what do you mean? And would it make a  
17 difference if you used one of the other versions of  
18 ArCom?

19 DR. BERES: ArCom, Ar stands for argon  
20 packaged. It's packaged in an argon package. Air  
21 is removed to reduce the amount of oxidation of the  
22 polyethylene while it's on the shelf. So we remove

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1 all of the oxygen from the package replace it with  
2 argon, and it's vacuum sealed.

3 Com refers to compression molded. So  
4 the polyethylene we use is compression molded. We  
5 either compression mold our bar stock, which is a  
6 unique method where we mold a bar. It's molded.  
7 Most of the other processes for making bar stock is  
8 an extrusion process, where it's an extrusion  
9 process to make a bar.

10 We compression mold the bar. So we  
11 compression mold the part. The part just happens to  
12 look like a bar, and then if the component is  
13 complicated enough, it has to be machined, but the  
14 starting material is power. It's compression molded  
15 into a particular generic shape, and then machined  
16 further to get the intricacies.

17 The other method of producing a part if  
18 the part is processable in a mold, you can directly  
19 mold the powder, put it into a mold, and mold the  
20 part as a finished component, but that requires that  
21 the part be somewhat generic enough that you don't  
22 have all of these intricacies that you just cannot

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1 mold.

2 DR. LI: Okay. Just one last, quick,  
3 detailed question. On your laboratory testing were  
4 the parts sterilized or not sterilized?

5 DR. BERES: I don't believe that's  
6 mentioned in the test reports.

7 DR. LI: So were they sterilized or not?

8 DR. BERES: I don't know the answer to  
9 that.

10 DR. LI: Because that could make a  
11 difference, particularly in your fatigue testing.

12 DR. BERES: We could go back to the  
13 original test reports.

14 DR. LI: Thank you.

15 CHAIRMAN HEFFEZ: I have a related  
16 question that perhaps Mr. Roman or Dr. Quinn could  
17 jointly answer. It's regarding the mating of the  
18 surfaces.

19 At the time of surgery you do your best  
20 effort to mate the surfaces, but clearly due to the  
21 access, sometimes it's difficult from a three  
22 dimensional point of view to mate them the way you'd

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1 really like.

2 So Part A of the question is have you  
3 had significant problems or not and how you have  
4 addressed them, and Part B of the question is was  
5 all of the fatigue stressing was done with them  
6 mated perfectly. Was any fatigue testing done with  
7 them mated incorrectly?

8 DR. QUINN: Okay. I'll answer the first  
9 part and Shawn will answer the second.

10 I think you're right. One of the most  
11 difficult parts of the procedure is mating the  
12 condyle to the fossa because we have to deal with  
13 the occlusion as well, and as I mentioned before, in  
14 approximately 20 to 25 percent of the cases I  
15 usually move it after that first mating, after I'm  
16 able to take the patient's mandible and move it.

17 Under anesthesia there is some issue as  
18 to is that the same muscle tone that the patient  
19 will have when they emerge from anesthesia. What we  
20 normally do is put the patient in fixation, go back  
21 and place the prosthesis, and there is a point where  
22 we want to place the prosthesis posteriorally in the

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1 fossa so that if there is any pseudo translation,  
2 you're starting in a more posterior position, which  
3 is why we angulated the head.

4 We've had the experience where under  
5 anesthesia a patient with light in the mating  
6 appeared to be adequate. This is the dislocation  
7 patient that we dealt with.

8 When the patient recovered from  
9 anesthesia, there was a relaxation of the muscle,  
10 and the condyle came forward, and we had to actually  
11 replace it. So we recommend actually at the time of  
12 surgery to check it with muscle tone and with full  
13 paralysis. So at the time we actually check it to  
14 make sure that visible when you use the sterile  
15 mandibular manipulator, you're looking at the mating  
16 of the condyle and the fossa, which you have to do  
17 in any system, whether it's custom or stock.

18 And there's where I think it's up to the  
19 surgeon to make sure that before they leave that  
20 operating room, it's optimal mating. But it is  
21 surgeon experience that can determine how well  
22 that's mated, and it should start in the more

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posterior aspect of the fossa.

2                   CHAIRMAN HEFFEZ: How do you judge the  
3 spacing? Because it's very difficult to judge it  
4 completely across the condyle, what the adequate  
5 spacing would be between the two surfaces.

6                   Actually it's a good question. Some of  
7 the older systems, in the Vitek System there was the  
8 recommendation that you put actually a small pad  
9 between the condyle and the fossa because it would  
10 seat with time, and that was true because it was  
11 compressible Proplast in that fossa.

12                   We are recommending that it's just a  
13 manual seating without any directional forces from  
14 the screws, which is an important question. If the  
15 screws are placed in the ramus offset, you can  
16 literally drive the prosthesis up against the fossa.  
17 So we use drill guides so that we make sure that the  
18 screws are placed passively.

19                   The other way you can tell whether  
20 there's excessive compression between the condyle  
21 and the fossa is literally move it, is to go back to  
22 the mandibular manipulator and move it under direct

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1 vision.

2 CHAIRMAN HEFFEZ: But what is the  
3 spacing that you're asking the two surfaces or there  
4 is no spacing?

5 DR. QUINN: There is no spacing. It's  
6 direct contact, and then using the drill guide so  
7 that the screws don't present any driving forces  
8 superiorally.

9 CHAIRMAN HEFFEZ: Okay.

10 DR. QUINN: It's a good question. We've  
11 had that problem with all of the other systems we've  
12 used.

13 CHAIRMAN HEFFEZ: Because you also have  
14 the problem really with the glenoid fossa. You  
15 initially had the cement to take out the void, but  
16 you really don't know how to judge the void without  
17 actually putting the cement in.

18 DR. QUINN: That's true.

19 CHAIRMAN HEFFEZ: So any thought given  
20 to, for example, using a template to know whether  
21 truly the void is significant enough in that  
22 particular case?

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1 DR. QUINN: Well, I think the whole  
2 issue of void was whether there was significant dead  
3 space that would lend to an increased rate of  
4 infection from hematoma formation in the dead space  
5 under the prosthesis.

6 CHAIRMAN HEFFEZ: Was it dead space from  
7 infection or stability of the prosthesis?

8 DR. QUINN: No, because the stability  
9 has to be tripod stability that's fit **regardless**  
10 whether there's additional void. If you have tripod  
11 stability, and remember the majority of stability  
12 comes from the zygomatic arch where the screws are  
13 placed, but you're right. There's no way once you  
14 fit it to estimate what the amount of void is under  
15 the presses.

16 CHAIRMAN HEFFEZ: Could Mr. Roman  
17 address the Part B?

18 MR. ROMAN: In Part B there was no -- in  
19 the fatigue testing there was no set protocol for  
20 specifically testing them out of alignment, but just  
21 the general nature of potting the components into  
22 the test fixtures. There was a little bit of

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1 variability there. They weren't exactly set up with  
2 each other.

3 And just a follow-up. It was listed in  
4 the testing reports that all of the components were  
5 manufactured and were gamma sterilized.

6 CHAIRMAN HEFFEZ: Do you see any  
7 advantage to testing it with offset? Because even  
8 though what position you have them in, even *if* you  
9 have them properly mated, the patient doesn't  
10 function with them properly mated. The patient  
11 really functions with them not mated.

12 MR. ROMAN: Right. There may be some  
13 justification for testing at not exact alignment.

14 CHAIRMAN HEFFEZ: Thank you.

15 Janine.

16 DR. JANOSKY: Janine Janosky.

17 The question was primarily -- I don't  
18 know who would prefer to answer them; probably Dr.  
19 Quinn and Dr. Sinn or Ms. Verstynen.

20 Two issues right now that I'm grappling  
21 with. The first is the follow-up, and the second is  
22 the use of two primary sites. So since we addressed

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1 both of those issues separately, why don't we look  
2 at the interaction of those two?

3 So my primary question is: at what  
4 point do you have at least 80 percent of your data  
5 available for follow-up? And then from which site  
6 are those coming in terms of proportions?

7 MS. VERSTYNEN: Mary *Verstynen*.

8 Going back to that patient  
9 accountability, at every time point we had better  
10 than 80 percent follow-up. So that answers the  
11 first question.

12 And obviously the study is pretty much  
13 Dr. Quinn and Dr. Sinn. There were only eight  
14 patients that were not part of that. I believe that  
15 probably one patient wasn't returned to follow-up  
16 from the eight. So the rest of them that were  
17 missing follow-up were either at Dr. Sinn's or Dr.  
18 Quinn's sites. It's just that the other sites only  
19 did one or two.

20 We had the one site that did five, and  
21 they have one patient that is truly lost. We can't  
22 locate her. So at all time periods we did have

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