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IN THE COURT OF COMMON PLEAS
CUYAHOGA COUNTY, OHIO

MARY LOU ZIMMERMAN, et al.,

Plaintiffs,

-vs- JUDGE BURNSIDE CASE NO. 399411

THE CLEVELAND CLINIC FOUNDATION,

Defendant.

Deposition of DONALD A. MALONE, JR., M.D., taken as if upon cross-examination before Laura L. Ware, a Notary Public within and for the State of Ohio, at The Cleveland Clinic Foundation, 9500 Euclid Avenue, Room P6-115A, Cleveland, Ohio, at 2:45 p.m. on Tuesday, August 22, 2000, pursuant to notice and/or stipulations of counsel, on behalf of the Plaintiffs in this cause.

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DONALD A. MALONE, JR., M.D., of lawful age, called by the Plaintiffs for the purpose of cross-examination, as provided by the Rules of Civil Procedure, being by me first duly sworn, as hereinafter certified, deposed and said as follows:

CROSS-EXAMINATION OF DONALD A. MALONE, JR., M.D.

BY MR. LINTON:

Q. Dr. Malone, hi, my name is Bob Linton. We met just a moment ago. Mark Ruf is my co-counsel in this case, and we represent Mary Lou Zimmerman and her husband in a case that's been filed against The Cleveland Clinic Foundation.

Have you ever had your deposition taken before?

A. Yes.

Q. Have you ever had your deposition taken before in connection with a malpractice case?

A. Yes.

Q. How many times?

MR. MALONE: How many times depositions or how many times in that limited fashion?

A. It's never been in a malpractice case against me. I've served as an expert witness on a number of occasions in malpractice cases and other cases. I don't recall the number of times, truthfully.

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Guessing, 10 to 15, but I don't know.

Q. Have you ever testified by deposition in your capacity as a Cleveland Clinic employee? Do you understand the distinction?

A. Yes, and I have.

Q. Did that case involve allegations of malpractice, not against you personally, but against another staff person at the Clinic?

A. Not medical malpractice. I don't recall any medical malpractice cases.

Q. And I trust you, yourself, have not been sued personally for malpractice?

A. That's correct.

Q. In the 10 to 15 times, guessing, that you've testified, has that been for physicians or has that been for patients?

A. I believe all but one were for physicians.

Q. Were any of those for other physicians here at the Cleveland Clinic, past or present?

A. Not that I recall.

Q. Did any of them involve psychosurgery?

A. No, they did not.

Q. Did any of them involve OCD?

A. Not that I recall.

Q. Did any of them involve informed consent?

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A. Not that I recall.
Q. What have you done to prepare for your deposition today?
A. I have reread my psychiatric evaluation of Mrs. Zimmerman.
Q. Anything else?
A. No.
Q. Have you ever reviewed any other part of the Cleveland Clinic chart besides your psychiatric evaluation?
A. No, I have not.
Q. Have you at any time reviewed any other part of Mary Lou Zimmerman's chart at the Cleveland Clinic?
A. No, I have not. Let me correct one thing. The other records I have reviewed, at the time of her evaluation I reviewed her records from Menninger.
Q. Did you keep copies of those records?
A. They should be in her chart, but I don't know.
Q. If they are not in her – when you say her chart, would that be the Cleveland Clinic chart?
A. The Cleveland Clinic chart here.
Q. Do you maintain a separate chart for her?
A. No.
Q. So any records, if they still existed, would be --
A. Would be a part of her Cleveland Clinic record.

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Q. Do you know for which hospitalizations at Menninger –
A. No.
Q. – you had records for?
A. No, I do not.
Q. Do you know the dates?
A. Unless it says in my – may I refer to that copy?
Q. Let me start off by saying this is an open book exam.
A. All I need is that copy.
Q. Exhibit 2 is the only record that you would have generated or reviewed in preparation for your deposition, correct? Bad question. Let me rephrase that.
Exhibit 2 is your psych evaluation?
A. That's correct.
Q. That's dated August 31st, 1998?
A. That's correct.
Q. I think it was dictated on that date?
A. Yes, as far as I know. I don't recall exactly, but I always dictate them the same day, so I would assume it would be the same day.
Q. And that's the only record you would have generated relating to Mary Lou Zimmerman, correct?
A. That's correct.

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Q. And that's the only document you reviewed in preparation for your deposition today?
A. That's correct, yes.
Q. Do you have any other -- strike that.
Did you have any handwritten notes you would have taken at the time of your interview and evaluation of Mary Lou?
A. Only such that would have generated this document and subsequently would have been thrown away. It just says that I reviewed records from Dr. Donelly, who she had been seeing for the past ten years, and her several inpatient hospitalizations at the Menninger Institute.
Q. Can you be any more specific as to which of Dr. Donelly's records you reviewed or which of the Menninger Institute hospitalizations you reviewed?
A. No, I cannot.
Q. Do you have any independent memory of what was contained in those records?
A. No, I do not.
Q. Do you know how it was that those records came to you?
A. I don't recall.
Q. Is your practice when evaluating -- strike that.
I would assume you would have evaluated, before

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Mary Lou Zimmerman, other patients for the possibility of psychosurgery?
A. I have done that.
Q. Is the practice to have the patient bring the records, or is the practice to have your office or the Cleveland Clinic obtain the records?
A. The practice is typically for the patient to have the records sent prior to their visit.
Q. I take it you did not review for purposes of your deposition any medical texts, journal articles, studies, statistics?
A. I did not.
Q. Did you as part of your evaluation of Mary Lou Zimmerman?
A. Not that I recall.
Q. Did you review any such authorities since this lawsuit was filed?
MR. MALONE: You mean as a part of his routine or for purposes of the lawsuit?
MR. LINTON: Either one.
MR. MALONE: He looks at medical literature on a regular basis.
MR. LINTON: Either one.
A. I'm sure I've read articles since then of severe obsessive-compulsive disorder, psychosurgery,

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surgical techniques, but not anything out of my routine.
Q. Do you have any teaching responsibilities?
A. At the Cleveland Clinic?
Q. Yes.
A. Yes.
Q. What do those consist of?
A. Medical students, residents.
Q. Any fellows?
A. On occasion we'll have a consultation fellow that I'll deal with.
Q. Do you maintain a personal file yourself on psychosurgery? And by psychosurgery, I mean any type of psychosurgery.
A. There's no file. As in past articles or patients?
Q. Not patients. Articles, literature, statistics..
A. I have a huge file full of papers, and I'm sure there are several numerous ones on psychosurgery or severe obsessive-compulsive disorder.
Q. Tell me how you file that information. You say you have a huge file. What would that file be called?
A. With these I would likely have them under obsessive-compulsive disorders.
Q. So you would have a subject file for obsessive-compulsive disorder?

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A. Yes.
Q. And would you have a separate file for psychosurgery or would that be part of your OCD file?
A. No, I don't believe I do. I believe it would be under obsessive-compulsive disorder. With the advent of technology, I don't file very many papers anymore, so it would probably be very old.
Q. Do you maintain any kind of computer database separate from a Medline or something you plug into?
A. No.
Q. What medical texts would you refer one of your students to, be it a medical student or a resident or a fellow, who wanted to know more about psychosurgery?
A. I wouldn't refer them to a medical text, I would refer them to certain journal articles.
Q. What journal articles would you refer them to?
A. There really aren't very many. There's older articles primarily. There was some stuff done at Mass. General in the past, experience with 200 some patients, which was written by a Dr. Balentine.
Q. And where was that published?
A. I don't recall.
Q. Aside from Dr. Balentine's article, do you have any other journal articles you would –

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A. Send them to, no.
Q. Do you know the title of Dr. Balentine's article, the substance?
A. Primarily experience of 200 some odd cases of severe – with I believe it's cingulotomy and anterior capsulotomy. I think both of those are in the title. But, you know, again, I don't know the exact wording. It's been a while.
Q. Dr. Balentine was a pioneer in the filed?
A. Certainly one of the first people to be doing anything for obsessive-compulsive disorder, yes.
MR. MALONE: You say "Balenteen," he says Baientine. I assume you're spelling them both the same way.
THE WITNESS: T-I-N-E.
MR. MALONE: It's all the same.
- - - -
(Thereupon, a discussion was had off the record.)
- - - -
Q. Do you know if the Balentine article discusses a procedure in which both a cingulotomy and a capsulotomy is performed?
A. I don't recall.
Q. Have you ever seen a cingulotomy or capsulotomy

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performed?
A. No, I have not.
Q. Do you know any of the details as to how it's performed?
A. No, I do not.
Q. Do you know to what part of the brain it's performed?
A. I understand where the anterior capsule is and I understand where the cingulate gyrus is.
Q. Would you be able to graph on a medical illustration where the surgery is performed?
A. I would be able to graph the anterior cingulate gyrus. I'm not sure I can point you to the anterior capsule.
Q. So, for example, if I showed you Plaintiffs Exhibit No. 3, do you recognize the middle showing a medical illustration of the limbic system?
A. Yes.
Q. You can obviously see there the cingulate gyrus?
A. Uh-huh.
Q. Is that just a yes for the Court Reporter?
A. Yes.
Q. Thank you. Are you able to diagram on there or mark on there where the anterior capsule is?
A. No, I don't believe I could exactly.

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Q. That's something you obviously have to rely on the expertise of neurosurgeons, right, right?
A. Yes.
Q. That's why they study neurosurgery and you study psychiatry?
A. You've got it.
Q. Are you able to tell us where on the cingulate gyrus the surgeon performs the cingulotomy?
A. No, I could not. I believe it's in the anterior part of it, but that's all I know.
Q. Again, that's something you have to rely on the neurosurgeons for?
A. My role in these cases is to assure that all reasonable medical steps, other than surgery, have been performed and they are indeed not responsive to those treatments.
Q. And is that your sole role in the consultation team?
A. That is my role.
Q. For evaluating a patient for psychosurgery at the Cleveland Clinic?
A. That is correct.
Q. Is that role published anywhere, is there any sort of written procedure, protocol, guideline here at the Cleveland Clinic?

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A. There is no published guidelines to that.
Q. Is it the unwritten guideline --what is the unwritten guideline or procedure for evaluating a patient at the Cleveland Clinic for psychosurgery?
A. It's to assure that they've received appropriate medication trials and either received or been resistant to specific psychotherapy in order to be called treatment resistant. There are very few medications that are effective in the treatment of obsessive-compulsive disorder as opposed to depression.
Q. What medications - I'm sorry, I don't want to cut off your answer. If you could just explain to me --
A. That really was my answer.
Q. - what the guidelines are at the Cleveland Clinic for evaluating for psychosurgery?
A. For obsessive-compulsive disorder, which is what I do, it would be basically doing exactly what I said, assuring that they've had appropriate medication trials and appropriate psychotherapy trial.
Q. And to form what ultimate conclusion?
A. That they will not respond to known effective treatments for obsessive-compulsive disorder. have not responded to them, and therefore have no other alternative.

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Q. Does the standard of care require in psychiatry, when evaluating an OCD patient for psychosurgery, that there be no known available treatment for the clients, effective medical treatment for the - let me rephrase that.
A. Please.
Q. Does the standard of care require that all known treatment modalities be exhausted before a patient goes to have psychosurgery performed?
A. That is not a Cleveland Clinic requirement, it is my personal feeling and recommendation and certainly that of those people in the field.
Q. That the standard requires that before surgery is considered?
A. Yes.
Q. What medications are available to treat OCD?
A. They're the serotonin reuptake inhibitors.
Q. Which ones?
A. There's Prozac. I'm giving you trade names, by the way. Paxil, Zoloft, Luvox.
Q. Can you spell that?
A. L-U-V-O-X. There's now a fifth one which was not available at the time of this evaluation, so it wouldn't have been an issue in this case, called Celexa, C-E-L-E-X-A, and there's another medication

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called Anafranil.
Q. Which was available then?
A. Yes.
Q. And what are the therapeutic dosages for each of those?
A. They're variable, depending upon the tolerance of the patient. Prozac typically we use doses of 20 to 60 milligrams a day, Paxil would be 20 to 50 milligrams per day, Zoloft would be 50 to 200 milligrams per day, Luvox wouid be 50 to 300 milligrams per day, and Anafranil typically is around 150 milligrams per day titrated to a blood level.
Q. How about Celexa?
A. It's not really well studied, it's in that category, but probably from 40 to 60 milligrams per day would be reasonable. There's not a lot of experience with that in obsessive-compulsive disorder, but it just happens to be in that group of medications.
Q. And how long does the patient need to be under these medications until a psychiatrist like yourself can determine that they're not responding?
A. Optimal response takes at least two to three months to achieve, however at optimal dosages if you go for a month or so and don't see any response at all, we

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begin to feel they're not going to respond and will often change treatment.
Q. What neurotransmitters are treated or affected by Prozac?
A. Serotonin.
Q. Is that with each of these?
A. That is correct.
Q. Which of these also treat depression?
A. All of them.
Q. How is it that the same drug treats depression and also can treat OCD?
A. Well, a number of these, of the antidepressants, are effective for various anxiety disorders, obsessive-compulsive disorder being one of those.
Q. How does that work?
A. Good question. We don't know.
Q. What's the theory?
A. We don't know. I wish I had a better answer for you, and there's a number of people working on it, but the fact of the matter is we don't know.
We think that serotonin somehow controls pathways in the cingulate gyrus going to the prefrontal cortex and the thalamus, but it's backwards reasoning. We don't know. We just know that they work.

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Q. Do you know the success rate of cingulotorny for OCD?
A. Not exactly, no. I mean, there have been a number of different numbers people give, but there's not a lot of experience. The ranges I've seen vary tremendously.
Q. From what to what?
A. Well, you'll have some series of a few cases with a hundred percent response and other larger series with 40 to 60 percent response. So they vary dramatically.
Q. Can you cite to any specific literature that publishes any statistics?
A. No.
Q. What do you rely on when you say --
A. Just, I mean, Balentine's article is certainly one historically often quoted. It's the largest in the series, that I'm aware of.
Q. And what is his number?
A. I don't recall exactly what it is.
Q. How about for capsulotomy, what's the success rate for capsulotomy?
A. Again. I don't know the specific numbers per various studies. There are ranges quoted, and again they're oftentimes quoted in a very small series of patients

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and it can be anywhere from zero to a hundred percent.
Q. So there is a lower success rate for capsulotomy?
A. Well, there may be one patient that didn't respond, zero or two patients that didn't respond.
Q. So there is some literature which shows a lower success rate for capsulotomy than cingulotomy?
A. No, not necessarily. That can be the case for either of the procedures.
Q. So the literature -- there's some literature for both procedures which shows there may be no person that responded to treatment?
A. There may be case reports of people that have not responded.
Q. And do you know the statistics for combined cingulotomies and capsulotomies?
A. I do not know.
Q. Do you know which is more effective for treating OCD?
A. No, I do not.
Q. Do you know which of the three is more effective, that is cingulotomy, capsuiotomy or combined cingulotomy and capsulotomy?
A. No, I do not.
Q. Again, you rely on neurosurgery for that?

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A. Uh-huh.
Q. That's a yes, just for the record?
A. Yes. I'm sorry.
Q. Is there any internal statistics, to your knowledge, maintained by the Cleveland Clinic on its success rate in psychosurgery?
A. Not to my knowledge.
Q. To your knowledge what psychosurgery is performed at the Cleveland Clinic, what procedures?
A. Cingulotomy, capsulotomy, combined cingulotomy/capsulotomy.
Q. Anyothers?
A. I believe there's some procedures on the thalamus for pain, but other than that I'm not really familiar with those. It's not my area.
Q. What about leukotomy, are you familiar with that procedure?
A. Not really.
Q. What about frontal lobotomy?
A. Historically I'm certainly familiar with the procedure. I'm not aware of it being performed.
Q. Based on just your experience and your studies, what is a prefrontal lobotomy?
A. Well, again, historically, thankfully is all I'm aware of, which is a rather destructive lesion of

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the prefrontal cortex which has rather significant blunting effects, a mood affect behavior that was done many years ago.
Q. Was that ever done in an attempt to treat OCD?
A. Not that I'm aware of.
Q. Do you know why cingulotomy works to treat OCD?
A. No.
Q. Do you know why capsulotomy works?
A. No.
Q. Do you know why a combination of the two would work?
A. No.
Q. Is it your understanding that a portion of the brain is destroyed during the procedure?
A. Yes.
Q. And that the brain cells are killed, irreversible death?
A. Yes.
Q. And how is that done?
A. I don't know exactly, other than I think there's stereotactic leads placed and damage done directly to the brain, but that's my total understanding.
Q. Were you aware that it was done by cooking those parts of the brain, to use Dr. Barnett's wards?
A. They cause destructive lesions. I don't know how or

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what.
Q. You don't know if It's burn, cook, cut, you don't know?
A. I do not know.
Q. What, based on your experience and your research, what percentage of the population suffers from OCD?
A. Estimates range anywhere from one to three percent of the population.
Q. And what percentage of OCD patients would have severe OCD?
A. I mean, it depends on the definition.
Q. Why don't we start with how would you define severe OCD?
A. Severe OCD is somebody who would score a severity rating of over 28 on what's called the Yale Brown obsessive-compulsive scale, but the more accurate definition is when it significantly impairs their ability to work, relate, live.
Q. You would not have reviewed - is it YBOCS?
A. Uh-huh.
Q. Y-B-O-C-S. You did not review the actual results of Mary Lou Zimmerman's YBOCS text, did you? I know you have the results listed: but you didn't actually review the test itself?
A. I think I probably gave it to her. I usually do.

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Q. Why don't you look at your report and tell us if you can for sure.
A. She was administered a YBOCS and scored 38 out of 40. I can't tell from that.
Q. And I assume you have no independent memory?
A. No, although often I do a YBOCS on people with OCD. It takes two minutes. It's very easy to do.
Q. How do you do a YBOCS test?
A. There's a scale, basically, which rates the severity of obsessions and compulsions on five different areas, and I just tear off sheets that you hand to the patient. They rate it and you score it.
Q. I assume you can't independently tell us how long you actually spent with Mary Lou Zimmerman?
A. No. Typically I have an hour -
Q. Wait. Let me just stop-you, just to be clear.-Do- you have an independent memory of this woman? By that, can you recall --
A. I cannot picture her, no.
Q. Can you recall any conversations you had with her?
A. No.
Q. You'd have to rely solely on what's in your report?
A. That's correct
Q. Typically, how long would you spend with a patient like Mary Lou Zimmerman?

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A. One hour. That's with the patient.
Q. And would that include, in this case, Mary Lou Zimmerman and her husband?
A. Yes. In reviewing this I understand her husband was present.
Q. How much time would you have spent reviewing her records?
A. It depends on the extent of the records.
Q. Since we don't know how extensive they were, you couldn't tell us?
A. I would have no idea, that's correct.
Q. Do you have an independent memory of discussing Mary Lou Zimmerman with anybody?
A. No, I do not.
Q. Do you know if you would have discussed her case with Dr. Barnett?
A. Certainly he would get a copy of this psychiatric evaluation.
Q. Look at the top of Exhibit Number 2. There's a fax number there. Do you see that?
A. Uh-huh.
Q. And a date.
A. Uh-huh.
Q. And I can't read upside down. What is that?
9-23-98. The number of the fax, do you recognize

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that fax?
A. That's my fax.
Q. That's your fax?
A. Uh-huh.
Q. You're not sure if you talked to Dr. Barnett, you don't have an independent memory?
A. No, I do not.
Q. And there's nothing in your record that confirms whether you talked to him or not?
A. That's correct.
Q. To try to reconstruct things as best we can, Dr. Barnett would have seen the patient, according to his record, on August 31st, 1998, the same day which you saw the patient. You reference in your report on page two that they are scheduled to meet with Dr. Barnett later today-and discuss the potential surgical risks
A. Uh-huh.
Q. Do you see that?
A. Uh-huh.
Q. Assuming that to be the scenario that unfolded, that the patient first saw you then went over to see Dr. Barnett, is it likely that you would have had a conversation with Dr. Barnett?
A. It's possible.

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Q. Or you just don't know one way or the other?
A. I do not.
Q. How quickly-- strike that. If you knew Dr. Barnett -strike that.
If you knew the patient was going to be Seen by Dr. Barnett, would you expedite the transcription in your report?
A. I may, although certainly the procedure wasn't scheduled for later that day.
Q. Right.
A. And so we have a lot of time in these cases and, you know, he may or may not have wanted my -- if I would have thought the patient was not a candidate I probably would have called over and said, Gene, don't bother. But aside from that, there's no reason that I necessarily would have contacted him or expedited this so he saw it ahead of time. He wants to know from me whether they've exhausted other options, in this case she had.
Q. Do you know who that would have been faxed to on March -- excuse me, on September 23rd?
A. No idea.
Q. So your role, as I understand it, is essentially to determine whether or not the patient is resistant to drugs and therapy?

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A. That's correct.
Q. And at that point then the patient goes to Dr. Barnett in neurosurgery, he decides whether she's a surgical candidate?
A. That's correct.
Q. You don't decide if she's a surgical candidate?
A. No.
Q. That would be solely Dr. Barnett's responsibility?
A. That's correct.
Q. And do you recall any conversations you had with Dr. Donelly or Dr. Hughes, two psychiatrists?
A. I do not.
Q. And anything in your records to show you would have had a discussion with them?
A. No.
Q. Is it your practice to have discussions with a patient's treating psychiatrist?
A. Only if the records I have reviewed are incomplete.
Q. Is there anything in your report that indicates the records may have been incomplete?
A. No.
Q. Did anybody else in psychiatry evaluate the patient besides you?
MR. MALONE: You mean in-house here at The Foundation?

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MR. LINTON Yes.
A. Not that I'm aware of.
Q. Are you aware of anybody else, besides you and Dr. Barnett, that evaluated the patient?
A. No.
MR. MALONE: You mean preoperatively, I assume?
MR. LINTON: Correct.
Q. Are you aware of any promotional materials, handouts, anything that the Clinic provides to patients who are considering psychosurgery?
A. No.
Q. Or cingulotomies or capsulotomy?
A. No, I do not.
Q. How do people find out the Clinic provides that service?
A. The most common way I've found is the Internet.
Q. On your webpage?
A. Well, not on our web page, but there's an exhaustive OCD network out there.
Q. Sure.
A. And once one procedure is performed by one hospital, the patients will send that around rather rapidly and we get e-mails and letters from all over.
Q. Have you had any input into providing information

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for the Cleveland Clinic web page -
A. I have not.
Q. - on psychosurgery and OCD?
A. No, I have not.
Q. Have you, yourself, published in the area o psychosurgery?
A. I have not
Q. Have you published in the area of OCD?
A. I have.
Q. Could you just read for us or identify on there all articles and --
A Okay.
Q. - any authorities that you would have published or assisted in publishing relating to OCD? And why don't we do this, I'm going to have you highlight just the numbers so we can keep track of that as you call off which ones.
A. Publication number eight is a case presentation of a patient I saw with one of the residents published in 1990 on severe obsessive-compulsive disorder. And I think that's it, but -- I edited a journal in 1999 which I hate to say, since I edited it, but I believe has a chapter on obsessive-compulsive disorder.
Q. What do you do as an editor?

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A. I don't recall if I invited all the people who wrote the chapters for the journal, but I invited some of them, certainly others may have been invited prior to my becoming involved with the project, but basically my responsibility is to set up which would be reasonably good chapters for primary care physicians, in this case to read what would be reasonable setup guidelines for what to write and have them go ahead and write the chapters, then I do the review of those.
This is the same one.
Q. For the record -- excuse me. For the record, Dr. Malone, when you say this one --
A. This is the issue, basically under book chapters and other publications, another publication.
Q. Let me just stop because the Court Reporter won't clarify what this is when you said this.
A. Number four under book chapters and other publications.
Q. And the same as number 16?
A. Is the total edition that I coedited. This was my own specific editorial in that edition.
Q. This being number 16?
A. That's correct. I don't recall if I have any abstracts on OCD in particular. No. I've given a

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number of talks on OCD, but no other abstracts or publications.
Q. Are those talks identified on your CV?
A. Some would be if they're grand rounds presentations.
Q. Why don't you go through what's listed on your CV to see if there are any other references to your involvement with OCD
A I gave grand rounds at Rockford Memorial Hospital in Illinois in March of 1995.
Q. Would you have written materials handed out as part of the grand rounds?
A. Not that I would have now. I may have sent some objectives and other things. I certainly would have at that point. There was one given in the Milwaukee VA Hospital, grand rounds, December, 1995. Fort Worth, Texas, 1996, Texas School of Osteopathic Medicine, Grand Rounds. Gave a talk in Chicago, 1998, to an International Latino Psychiatric Association on obsessive-compulsive disorders. Gave a talk in May of 1999 locally. Gave a talk in November of '99 on obsessive-compulsive disorder in the workplace to the International Employee Assistance Professionals Association.
Q. Thank you. In any of your presentations did you

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address psychosurgery as a treatment option for OCD?
A. I don't recall specifically.
Q. Did you address psychosurgery as a treatment option for OCD in any of your publications that you authored or edited?
A. I do not believe so.
Q. And is there a reason why you didn't?
A. Not other than they were medication focused. They weren't exhaustive reviews.
Q. Could you describe the type of psychiatric practice you have?
A. I do a mixture of teaching, research and clinical practice. I'd say about 70 percent to 75 percent of my practice is clinical, direct patient care. I direct the mood and anxiety disorder clinics here. A large part of the anxiety disorder clinics being panic disorder, obsessive-compulsive disorder patients. I do a lot of consultation work for psychiatrists locally, nonlocally.
Q. You said 70, 75 percent clinical practice. What percentage would you say is teaching and research?
A. Probably it would be about 10 percent research and the rest would be teaching.
Q. Do you currently have any research projects underway

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In OCD?
A. No, not currently.
Q. Any that you've been involved in previously?
A. No, other than the one published patient, which was really a case report.
Q. A case report in a single patient?
A. That's correct.
Q. Any grant money that you've received to study OCD?
A. No, not to this point.
Q. Any you've applied for?
A. We do have a grant we're hoping to receive looking at the treatment of obsessive-compulsive disorder, yes.
Q. Can you give me some idea percentage wise what percentage of your patient population would have OCD as a diagnosis or as the primary diagnosis in their condition?
A. 10 to 15 percent.
Q. Can you give me some idea of the number of patients that you've treated that have OCD either as a primary or secondary diagnosis?
A. Certainly over a hundred.
Q. What is OCD?
A. It's a disorder. Again, we think of the part of the brain that you were talking about earlier.

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Q. That being?
A. Where certain parts of the limbic system –
Q. That being?
A. The cingulate gyrus. We actually have seen PET scans where patients will have hyperactivity in the inferior frontal cortex, the cingulate gyrus, that actually normalizes with effective treatment, medication or psychotherapy. It's a disorder where people have obsessions and/or compulsions, usually both, which take up a great deal of their time and impair their lives in other areas, areas of work, relationships, family.
Q. Do we know why they have that disorder?
A. We certainly know it's hereditary, beyond that, no.
Q. Do you know what parts of the brain cause OCD or control OCD behavior?
A. No.
Q. You said you've treated over a hundred patients with OCD. If you give me a typical year, how many patients would you see in a given year with OCD? Again, an estimate.
A. Separate patient visits or different patients?
Q. Let's say different patients.
A. I'm guessing 40 would be a guess.
Q. How many patients have you evaluated for

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psychosurgery?
A. I think six or seven.
Q. How many would you have evaluated at the time of Mary Lou Zimmerman's evaluation?
A. I think three.
Q. Would she have been number three or number four?
A. I don't recall.
Q. How was it that you came to have that role as the psychiatrist responsible for evaluating a potential psychosurgery candidate?
A. One of my specialties is obsessive-compulsive disorder, so that would be the role, that would be the way.
Q. Is there some sort of --
A. If it was another diagnosis, it could well be another psychiatrist.
Q. Was it your understanding that she was coming to the Clinic to be evaluated for the possibility of psychosurgery?
A. I don't recall. I mean, from the reading of this, my answer would be yes.
Q. And that's what I'm trying to find out. Were you part of a team or a committee that was put together to evaluate potential --
A. No.

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Q. -- psychosurgery patients?
A. No.
Q. This patient was an OCD patient, that's one of your specialties, so that's why she was assigned to you?
A. That's correct.
Q. Did you receive any special training on how to evaluate patients for psychosurgery, other than your psychiatric training and experience in OCD?
A. No.
Q. Have you attended any CME seminars or APA seminars that addressed the issue of psychosurgery?
A. Certainly there have been conferences on OCD that I've attended over the years that talk about psychosurgery as an option. I don't believe there's been any CMEs strictly on psychosurgery.
Q. How about CME seminars or APA seminars on how to evaluate a patient for psychosurgery?
A. Other than what wouid have been addressed in those that I mentioned, no.
Q. Can you tell us of a specific seminar that you attended in which psychosurgerywould have been discussed in connection with OCD?
A. I can't recall one, no.
Q. Do you keep a file for your certification purposes of CME seminars you attend?

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A. Yes, but the APA would simply say APA until you get 40 hours of CME. It wouldn't have each individual.
Q. Do you keep or make it a practice to keep research materials or handouts you receive from those seminars?
A. If they're valuable to me.
Q. Can you think of anyone that addressed the issue of psychosurgery with OCD?
A. Not that I recall.
Q. You trained at Mass. General?
A. Uh-huh.
Q. Was Mass. General performing psychosurgery at the time of your residency?
A. Yes.
Q. Were you involved at all in that?
A. No.
Q. Were you involved at all in evaluating potential psychosurgery candidates?
A. No.
Q. Were there people in psychiatry that you worked with or trained under who were?
A. Yes.
Q. Who was that?
A. There would have been a number of them. I believe at that time our chairman, Ned Cassem, C-A-S-S-E-M,

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was the head of that committee.
Q. That committee being –
A. They had a committee to evaluate patients for psychosurgery. Whether that exists now or not, I don't know, but that was obviously 12, 13 years ago.
Q. Is there any comparable committee like that here at the Cleveland Clinic, to your knowledge?
A. Not that I'm aware of.
Q. Is there --don't be afraid to blow your own horn. Is there anyone more qualified presently in OCD here at the Clinic other than yourself?
A. I don't believe so.
Q. Do you know --strike that.
When would you have performed your first evaluation for psychosurgery here at the Clinic?
A. I don't know.
Q. Well, Mary Lou Zimmerman was in '98. Would you have been doing it before 1995?
A. No.
Q. How about before '97?
A. It's possible. I don't recall. I would guess a year, year and a half, two years before this, but that, again, I'm guessing.
Q. When you say you guess that, are you somehow

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thinking of a change in your responsibilities or anything?
A. No.
Q. That's just your memory?
A. Right.
Q. How did they start performing psychosurgery at the Cleveland Clinic for OCD; do you know?
A. No, I don't know.
Q. How did you first become aware of it?
A. My best recollection is I had a talk with Gene either when I was talking to neurosurgery about something unrelated or something and he said he had an interest in it.
Q. Would that have been within approximately a two-year window before you saw Mary Lou Zimmerman?
A. I'm guessing, but yeah.
Q. Did you bring it up or did he bring it up?
A. I don't recall.
Q. But somehow you knew that it was out there as a possible treatment option and –
A. Oh, yeah.
Q. -- you discussed it with Gene?
A. Uh-huh.
Q. What, to the best of your memory, was discussed? I mean the substance of the conversation.

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A. I don't recall, other than he had an interest. Certainly I see my share of treatment resistant OCD, which is sent here from all over.
Q. Do you know if anybody else here at the Clinic besides Dr. Barnett is performing psychosurgery for OCD?
A. Not that I'm aware of.
Q. Just to speed things up, I was told before the start of your deposition you didn't have any involvement with the patient after the evaluation of August 31st; is that right?
A. That's correct.
Q. Is there any protocol or procedure for following up patients like Mary Lou Zimmerman once they are evaluated and have psychosurgery at the Clinic from a psychiatric standpoint?
A. From a psychiatric standpoint, only if they're local and do not have a psychiatrist.
Q. The understanding is she would be followed by her home psychiatrist once she was discharged?
A. That's correct.
Q. Have you ever, of the six or seven patients that you've evaluated, have you found any were not candidates for psychosurgery or that there were other alternatives besides surgery available for

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those patients?
A. I need to correct something if I misspoke.
Q. Sure.
A. I've evaluated more patients than that. These are patients that actually went through with psychosurgery.
Q. I see. So of the six or seven have been he numbers that actually went through for psychosurgery?
A. That's correct.
MR. MALONE: That he's referred.
A. That I've referred.
Q. That you've evaluated. And how many patients would you have evaluated as potential candidates for psychosurgery?
A. I don't know. I see -- I will frequently see people who come here referred for treatment resistant obsessive-compulsive disorder where psychosurgery has been thought of as an option by their psychiatrist, so that would be -- I don't know exactly how many, but that would be a much larger number.
Q. Are you able to estimate in any sort of range?
A. Most of those 40 patients I see every year are referred to me for treatment resistance. Very few come in as their first shot at treatment, but not

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all 40 of those obviously per year get referred because of psychosurgery.
Q. That's what I'm asking. How many would you see -
A. Exclusively referred?
Q. Exclusively referred.
A. I'd say double the number that went through.
Q. Have you, aside from that group of patients, have you recommended psychosurgery to any of your other patients that you're treating for OCD?
A. One of the patients I evaluated was my own patient.
Q. You said that you evaluated. Did you determine as the treating psychiatrist that --
A. Right, I was the treating psychiatrist. You changed the word on that, but, yes, as the treating psychiatrist we had exhausted all other options.
Q. Is electric shock ever used to treat OCD?
A. On occasion it's used. It is not thought to be effective.
Q. Have you -- is electric shock available here at the Cleveland Clinic?
A. Yes.
Q. Have you ever performed electric shock or had it performed on any of your patients with OCD?
A. I've certainly seen patients who have had ECT performed in the past. I do not recommend ECT for

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my own patients with OCD.
Q. Do you recommend the ECT for any of your own patients?
A. Yes.
Q. For depression?
A. Yes.
Q. Is there support in the literature for the treatment of OCD by ECT?
A. There really isn't much. On occasion you'll get a case report that somebody responded, but most of the literature in OCD is pretty clear that ECT is not an effective treatment.
Q. Do you know whether or not Mary Lou had ECT?
A. Unless it's in this record, I would not know.
Q. It's not something you would ever recommend a patient try before --
A. No.
Q. -- undergoing psychosurgery?
A. No, I would not.
Q. When you have -- of the patients you specifically have seen to evaluate for psychosurgery, why have you recommended against the surgery?
A. The only reason I would recommend against the surgery would be they had inadequate trials of either medication and other psychotherapy.

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Q. Ever refer any patients to a neurosurgeon outside the Cleveland Clinic for psychosurgery?
A. No, I have not.
Q. And all the psychosurgery patients that you've evaluated and decided there was no other medical treatment would have been referred to Dr. Barnett?
A. That's correct.
Q. Do you know what his experience and expertise is in performing psychosurgery?
A. No, I do not.
Q. Do you know how many procedures he's performed?
A. No, I do not.
Q. Do you know his success or complication rate?
A. No, I do not.
Q. Are there other institutions more qualified to perform psychosurgery?
A. I do not know.
Q. You don't know, for example, that Mass. General would be more experienced in psychosurgery based on what you learned during your residency?
MR. MALONE: I'm going to show an objection. I don't think experience equates to competence, but you can answer the question.
A. Balentine certainly had vast experience, but to my knowledge he's no longer practicing psychosurgery at

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Mass. General. Again, that also doesn't equate to competence, and it dates me a little bit, but it doesn't equate to competence.
Q. What neurosurgeons do you know of who perform or have performed psychosurgery?
A. The only ones I know of, other than Balentine -obviously-at-Mass. General,-I-don't know-but I've heard of Cosgrove at Mass. General and that's it.
Q. And Dr. Barnett, obviously?
A. Yes. that's correct.

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(Thereupon, a discussion was had off the record.)

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Q. We've covered this already --
A. One more thing i need to-clarify. There is a new neurosurgeon on our staff, Ali Rassi, who also I know has performed psychosurgery.
Q. Do you know about his expertise or experience?
A I really don't to any significant degree.
Q. i think we've covered this, in essence, but in summary, you rely on neurosurgery to decide if the surgery is appropriate, correct?
A. That's correct.
Q. You rely on neurosurgical expertise to decide if the

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patient is an appropriate candidate?
A. That's correct.
Q. The neurosurgeon decides the type of surgery to perform?
A. That's correct.
Q. You have no expertise to recommend the type of psychosurgery or even if psychosurgery should be performed?
A. That's correct.
Q. Are you aware of any clinical trials on cingulotomies and capsulotomies combined?
A. On that specific procedure?
Q. Yes.
A. No.
Q. Anyanimal studies?
A. Not that I'm aware.
Q. Animal studies are used from time to time to study, for example, drugs in psychiatric conditions; are they not?
A. Certain conditions, conditions they can mimic.
Q. Do you know if the psychosurgeries performed at the Cleveland Clinic are approved by Medicaid or Medicare?
A. I do not know.
Q. Do you agree that psychosurgery is controversial

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even today?
A. Amongst who, the lay public?
Q. Amongst the medical community.
A. Well, certainly psychosurgery has a long history in the lay community, a rather sordid history, so obviously it's controversial in that respect. I would say amongst psychiatrists who treat OCD it's not very controversial simply because we see the patients that simply don't respond to anything else whose lives are run bytheir OCD, high suicide rates, other kinds of things that just really leave us no good alternatives.
Q. By the way, Mary Lou Zimmerman was not a high suicide rate, was she?

MR. MALONE: A high suicide rate or risk?

MR. LINTON: Risk. Thank you.

A. Unless it says in here, I do not know. I don't recall.
Q. Why don't you take a look at your report and see, first of all, if she was a high suicide risk. Is that something you would have noted in your report; is that an important piece of information when evaluating a patient?
A. That's an important piece of information, though it

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would not change my recommendation for her.
Q. If you look at the mental status examination, second last sentence.
A. Okay. She's had some suicidal thoughts in the past, nothing currently.
Q. So you did not consider her a suicide risk at the time of the evaluation?
A. At the time of the evaluation, no.
Q. And the sole determination you made is that her OCD was treatment resistant, correct?
A. That'scorrect.
Q. You didn't evaluate the depression or risk of suicide or anything else like that, did you?
A. That's correct.
Q. Under your diagnosis you deferred an Axis II diagnosis; that's correct?
A. Yes. *Axis* II, personality order diagnoses, are made over the long term, and I think you'd have to know somebody more than one session.
Q. You didn't rule out the possibility that she had a personal disorder; is that correct?
A. That's correct.
Q. You did not rule aut the possibility *of* depression; is that correct?
A. That's correct.

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Q. If she, in fact, was depressed would you have been in a position to make that diagnosis?
A. I would have if she had -- oftentimes people have depressive symptoms with their OCD. If she had a separate diagnosis, I would have noted it.
Q. And you did not note any separate depressive symptoms?
A. Not according to my workup.
Q. Do you know what fiber tracts are actually destroyed during the psychosurgery?
A. No, I do not.
Q. We may have covered this already, excuse me if I'm repeating myself, but you don't know how big the actual lesion is that's created, correct?
A. I do not.
Q. Have you followed up with any other patients that you have -- strike that.
Have you followed up with any other patients who have had psychosurgery performed here at the Cleveland Clinic with OCD?
A. Yes.
Q. How many patients?
A. I followed up with two of them.
Q. And when was the surgery performed in those patients?

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A. One was approximately a year and a half ago or a little over a year ago, the other would have been the first patient, so it probably would have been three years ago. I have not followed with either one recently.
Q. When did you last follow the 1997 patient?
A. It's been a couple of years.
Q. So you would have followed them for about a year or so after surgery?
A. I don't think I even followed them that long. I saw him once or twice postoperatively.
Q. And how about the 1999 patient, how long did you see that patient postoperatively?
A. The last time would have been about four months ago.
Q. So that would have, likewise, been a year after the surgery?
A. Yes.
Q. How long does it take for the full effects of psychosurgery, if successful, to materialize?
A. Like other patients for OCD, it can take several months.
Q. What was the status in terms of success rate of those two patients, in your judgment?
A. The first one was improved, significantly improved,

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the second one was partially improved for the OCD.
Q. And how would you define significantly improved?
A. The first person had a greater than 50 percent decrement in their YBOCS score.
Q. And how about partially?
A. I believe the second person had about a 20 percent decrement.
Q. Any side effects that you were aware of from the surgery?
A. With the --
Q. I'm sorry. Specifically with these two patients, did either of them suffer side effects?
A. Psychiatric side effects of the surgery?
Q. Any kind of side effects, psychiatric or otherwise.
A. Yeah, one had -- the second one had an infectious complication.
Q. Do you know what organism?
A. No, I do not.
Q. Do you know were there any -- do you know the cause of the infection?
A. I do not.
Q. Was Dr. Barnett the same surgeon that performed that surgery?
A. Yes.
Q. Do you know what procedure was performed on that

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patient?
A. I do not recall.
Q. Either a cinguiotomy, capsulotomy or a combination?
A. That's correct.
Q. Do you know if there were any long-term effects from the Infection?
A. She initially had some air as a result of the infection which --some air introduced as a result of infection, sometimes you get air, and there were some neurocognative deficits requiring some rehab. I don't know how she's doing now.
Q. You don't know If they're permanent?
A. There was improvement.
Q. But not resolution at the time you last saw her?
A. At the time I last saw her, no, not complete resolution.
Q. Aside from those two patients, and now we know Mary Lou Zimmerman would be patient number three, are you able to tell us the success or complication from the patients that have undergone psychosurgery that you have recommended to Dr. Barnett?
That was a bad question. Did you understand the question?
A. No.
Q. Okay. I'll object to my own question there.

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You said that your best memory is about six or seven patients that you've treated specifically for or evaluated specifically for psychosurgery that have actually had the psychosurgery. I want to see how they responded to that surgery, and you've discussed these two patients plus we know about Mary Lou Zimmerman. Are you able to tell us about any other patients in terms of their success or complications from the procedure?

A. Other than one that I've talked to their psychiatrist who had a good response.

Q. That would be based on secondhand information?

A. That's correct.

Q. Not based on your own evaluation, correct?

A. That's correct.

Q. And how long ago -- how long after the surgery did you have that discussion with the psychiatrist?

A. The discussion was at the APA, the surgery was approximately six months prior. The APA was in May.

Q. Now, I assume you don't have an independent memory of any discussions you had with Mary Lou Zmmerman and her husband concerning the risks and complications of this procedure?

A. That's correct.

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Q. You'd be relying upon what you typically tell a patient?

A. That's correct.

Q. What would you have told Mary Lou Zimmerman based on your practice and custom concerning the potential risks and benefits from a psychiatric prospective of a cingulotomy?

MR. MALONE Now, I want to just interpose an objection and make it clear that he's already testified that he does not endeavor to advise patients of surgical risks. These are psychiatric factors only, which is his area as a psychiatrist.

Q. That's correct what Mr. Malone just said, correct?

A. Correct, and I certainly don't discuss the surgery or any of its potential risks because I don't know them. The only risks and benefits I discuss are the risks of -- what are the potential risks of continuing on with your OCD, the debility of that versus the potential risks of surgery, for which I would refer them to Dr. Barnett.

There certainly is the risk that it won't work. I discuss that with them, although I tell them very clearly that we don't know what that exact percentage is, we really don't, not enough data out

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there to suggest who's a good candidate, who's not, you know, for response.

And the potential benefit being significant improvement in their OCD, although I also temper that, as I do with any OCD treatment, that cure is rare with medications or with surgery, and I think it's important that people understand that with OCD that cure is not common.

Q. Even by psychosurgery?

A. By any modality, a hundred percent improvement is unusual.

Q. Well, what are you expecting if the surgery is successful?

A. Well, the literature with OCD on medications considers a responder somebody who has improved 25 percent.

Q. On the YBOCS?

A. That's correct. That's a responder.

Q. And would you --

A. A significant responder is a 50 percent improvement.

Q. Would you --

A. That's what I talk about as a significant response to any treatment modality with OCD. Surgery as well.

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Q. You would not give a percentage success rate, possible success rate, to the patient of the surgery or would you?

A. I would not.

Q. Would not. You don't say that based on literature there's a 50 to 100 percent or 0 to 100 percent; you don't cite statistics?

A. I don't.

Q. You don't talk about complications?

A. That's correct.

Q. Other than it may not work?

A. That's correct.

Q. When you determine that cognition is grossly intact, how do you determine that in a patient like Mary Lou Zimmerman?

A. What I do in this type of evaluation, I don't do a full cognitive evaluation. What I will do is orientation to determine if a patient is oriented to time, place, person. I test memory to see if a person can recall three objects after ten minutes' time, and throughout the history you can assess their level of, for example, fund of knowledge.

Q. Their what?

A. Fund of knowledge.

Q. Fund?

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A. Fund.
MR. MALONE Fund, F-U-N-D.
A. F-U-N-D of knowledge, basic facts. I won't ask them in particular, but as you go along they will be able to provide accurate historical information for one thing or names of medications or other things that generally would present an intact sensorium - cognition.
Q. But in terms of formal evaluation, it would consist of orientation to time, place and person and a memory test of three objects after ten minutes?
A. That would be correct. In this case, I asked her to perform serial sevens, but she didn't have the motivation to calculate that.
Q. What do you measure in serial sevens?
A. Basically ability to concentrate and intent. Serial sevens is counting back from a hundred by sevens. in a person -- that doesn't really test math ability, although it certainly does too, but it tests a person's ability to focus and concentrate for a sufficient period of time to complete the test.
Q. And why did you say she wasn't motivated to perform that; what do you mean?
A. She must not have wanted to, for whatever reason, or

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just sometimes patients who are sick enough will simply say I'm not going to do that.
Q. in her case, why she didn't -
A. No idea.
Q. Again, so I'm clear, the cognitive test would have consisted of orientation to time, person, place, three-object memory test, and a request to do a serial seven test, correct?
A. Uh-huh.
Q. If you had wanted to do a full cognitive evaluation, what would that have consisted of?
A. For that I would have sent them to a neuropsychologist to do full testing.
Q. How many neuropsychologists do you have on staff at the Cleveland Clinic?
A. Three or four. I think we have three in our department.
Q. All of them, I assume, you have confidence in?
A. Yes.
Q. Is there any reason why she could not have been seen for neuropsychoiogical testing, had that been arranged by you or someone else at the Clinic?
A. I mean, anybody can be seen.
Q. Has it ever been the protocol or the guideline when evaluating a patient for psychosurgery at the Clinic

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to have neuropsychological testing performed?
A. Not to my knowledge.
Q. Help me out with something in your report. i'm looking at page one under history of present illness. If you go down to the last -- about the third last sentence it reads, "The symptoms have improved at times over the years, but have always been present, and essentially have worsened over the past 30 years." What does that mean?
A. Oftentimes with obsessive-compulsive disorder, as with a number of psychiatric conditions, their severity waxes and wanes over time. So it would not be unusual for symptoms to improve over their worst, stili being sufficiently symptomatic to impair functioning and then gradually over time that waxing and waning becomes lower and lower on the functionality scale,
Q. Did you do anything to measure her on the functionality scale besides the YBOCS test?
A. No.
Q. Does the YBOCS test measure functionality?
A. No, it does not.
Q. It only measures the severity of the condition?
A. That's correct. Basically with functionality -- there's no specific functionality test for people

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with OCD, but it's her ability to function in her life that's more significant. Can she hold a job, is she able to interact with family, is she able to maintain her marital relationship, et cetera, et cetera.
Q. Is there any way to test or evaluate functional capacity as it relates to OCD?
A. There's no scale, I'm aware of, that does that.
Q. Do you know why she was not able to work?
A. I don't know in particular, other than she's obviously spending several hours a day on her obsessive-compulsive behaviors.
Q. How do you know that?
A. She finds herself washing laundry many hours - let me make sure that that's a current one. Well, she's unable to go out of her house and do things. If she goes out she's afraid a car will run over something dirty in the street, the car will then be contaminated, she will then not be able to ride in the car again.
So there's these contamination fears that really permeate her ability to function outside the home, which limits her ability, obviously, to work. Washes laundry many hours a day, can't be touched by others.

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Q. Well, let me stop for a minute. Let's try to break this down, if we can. First of all, you talked about her being unable to go out of the Rouse. Does your report say on occasion she'll be able to go out and do things?
A. Uh-huh.
MR. RUF: You need to give a verbal-
answer.
Q. You need to say yes, if you can.
A. Yes, she says on occasion she will be able to go out.
Q. Are you able to say how often she was able to go out of the house?
A. No.
Q. From--
A. Not from this.
Q. And you talked about doing laundry several hours a day. Do you know if that's a historical factor that was a present fact being conveyed to you?
A. I'm not entirely clear. It says it progressed, so I'm assuming that it's at least as bad now as it was before, but i don't know that.
Q. And again, so I'm clear, you don't know why she was no longer able to work, in other words how specifically her OCD impacted on her job functions?

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A. Other than the points I mentioned, no.
Q. Well, you talked about having to wash laundry and being unable to go out of the house on occasion. Anything else?
A. Well, it says on occasion she is able to go out of the house.
Q. I assume on occasion she was able to go out of the house, according to your evaluation?
A. That's correct.
Q. In terms of her medications, if you can turn to that, please, the second page of your report. The time she came to see you, what were her present-- first of all, what was her obsession?
A. Again, I'm taking all of this from my evaluation.
Q. I understand.
A. I mean, her obsession is primarily contamination.
Q. What is her compulsion?
A. Well, there are a number of compulsions.
Q. Outline for me Mary Lou Zimmerman's compulsions when she came to see you.
A. According to this document -- compulsions are, just so I can be clear, basically responses to an obsession. It's a behavior targeted at reducing the anxiety brought about by the obsession.
So cleaning house would be a compulsion,

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extensive house cleaning, frequent washing of laundry is a compulsive ritual in response to the obsessions. Being unable to touch other people, if you do touch somebody to have to wash compulsively. For example, the inability to shake my hand prior to the appointment is a behavior targeted at avoiding the obsessive anxiety. Difficulty with leaving the house because of the potential contamination of a car or herself is a ritualistic avoidance behavior.
Q. Are you done with your answer?
A. Uh-huh.
Q. Is that a yes?
A. Yes.
Q. Do you know how much time she spent cleaning her house?
A. At this particular point in time, no.
Q. Do you know at the time she came to see you how much time she spent washing her laundry?
A. No, I can't tell by this evaluation.
Q. Do you know whether she was completely unable to touch others or only occasionally unable to touch others at the time she came to see you?
A. No, I can't tell from this evaluation.
Q. Are you able to say, I think you answered this already, but you're not able to say how often she

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was able or unable to leave the house?
A. That's correct.
Q. She did report to you that she was still engaged in sexual relations with her husband, didn't she?
A. I have to find that.
Q. Did she report that she had some sexual dysfunction related to the medication she was on, the Anafranil? I'm on page -
A. Right, she wasn't currently on that, so that may have been historical as well.
Q. So you don't know whether she was able to engage in sexual relations at the time she came to see you or not?
A. That's correct.
Q. If we can go down to the medication list, the second page of your report. First of all, the Anafranil, is that a recognized medication for treating OCD?
A. Yes.
Q. It was reported to you that that was --
A. She's not on Anafranil though.
Q. I'm sorry.
A. She's not on Anafranil at the time of this evaluation.
Q. I understand. I'm referring to -- I don't mean to confuse you. I'm at the top of your report. She

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stated the best medication overall was the Anafranil?
A. *Yes.*
Q. And that is recognized as a drug for treatment of OCD?
A. That's correct, yes.
Q. -The problem she had was-sexual dysfunction, bladder- incontinence?
A. *Yes.*
Q. Are there other medications that can be provided that would help treat the sexual dysfunction or incontinence and still allow the patient to take the Anafranil to treat the OCD?
A. Both of those are very difficult to treat. There are some other medications which can be tried.
Q. Such as?
A. For the sexual dysfunction, there's some trials with things like Periactln, but they're not often successful. The bladder incontinence I'm less familiar with. I don't treat that myself. I'll refer them.
Q. Do you know whether there was any attempt to treat Mary Lou Zimmerman with the Anafranil and other medications that deal with the side effects the Anafranii was causing?

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A. I don't know from this evaluation.
Q. If you go under medications, the first question I have for you, have you ever treated any other patient that's had this specific combination of meds?
A. Exactly, including Prinivil Premarin, Ateno'bl
Q. *Yes.*
A. Which are used for other reasons, obviously.
Q. *Yes.*
A. I don't recall if I've treated anybody with this exact combination.
Q. This is an unusual combination of medications for an OCD patient?
A. No, not actually for the patients that I'm sent. For them to be on several different classes of psychotropic medications is not unusual.
Q. Do you know the interactions that all of these drugs would have on Mary Lou Zimmerman?
A. Certainly I know there are some interactions we're wary of when using these combinations, but they're commonly used.
Q. Are you aware though of the interactions of all of these drugs?
A. Interactions with each other?
Q. Correct.

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A. Yes.
Q. Specifically when you have all of these drugs combined.
A. Yes. For example, Prozac can increase blood levels with Tegretol.
Q. Well, I'm not sure we're on the same page here. If you can't recall ever-treating a patient that had all this combination, how do you know the effect that all of these medications together would have on this patient?
A. Oh, the exact effect on this patient?
Q. Exactly. You were saying you know --
A. I wouldn't - I mean, you can't predict any Combination a patient - medications will have on any particular patient.
Q. Including this patient with this combination?
A. Exactly.
Q. Do you know if she was ever on a drug free trial?
A. I don't recall.
Q. She was able to provide an adequate history for most things, is that right, looking under your mental status examination?
A. Yes, that's what it says.
Q. Do you know which things her husband had to help her out with?

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A. I don't recall.
Q. Are you able to identify all the treatment Mary Lou Zimmerman received before she was evaluated by you for her OCD?
A. I don't recall.
Q. What type of therapy, psychotherapy, is effective, in your judgment, for the treatment of OCD?
A. Behavior therapy.
Q. What specific type of behavior therapy?
A. In particular, exposure therapy is the most effective type of behavior therapy.
Q. And for what period of time would you have a patient undergo exposure therapy and at what frequency before you would determine that that patient was nonresponsive to that type of therapy?
A. There's no absolute time limit.
Q. In your judgment.
A. It depends on the ability of the patient to do the behavioral techniques. For some the anxiety generated is far too great for them to be able to proceed with the therapy. For those individuals it might be shorter than somebody who's actually able to follow through with the techniques effectively and you can advance their techniques. For them it may be as much as six months, for others it may be

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much shorter than that if they're unable to tolerate it.
Q. When it is an effective -- let me back up. You're saying it can be determined, sometimes it takes six months, other times it takes less than that to determine if exposure therapy will be successful?
A. That's correct.
Q. When it is working how long does it take a patient to undergo exposure therapy to obtain therapeutic results?
A. Different patients respond in different intervals, and it may be six months for one patient and a year for another patient.
Q. Do you know if Mary Lou Zimmerman ever underwent exposure therapy?
A. I don't know from this evaluation. Well, let me read the past history one more time just to make sure. She had extensive cognitive behavioral therapy, which is a term - which is the type of therapy of which exposure therapy is one variant.
Q. But cognitive behavior therapy is broader than exposure therapy?
A. It's somewhat broader, yeah. With regard to OCD, it most often refers to exposure therapy.
Q. But you don't know --

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A. But the sentence that states, "Apparently the cognitive behavioral therapy has been frustrating to both she and the therapist because of her inability to confront her fears." Having her confront her fears is exposure therapy, so I would assume she would have exposure therapy.
Q. Did you know? You're assuming that, but you don't know if she had exposure therapy as part of her cognitive behavior therapy?
A. She was asked to confront her fears. That's exposure therapy.
Q. So your answer is you are sure that her therapy included exposure therapy?
A. Based on this, yes.
Q. And how long did she undergo the exposure therapy for?
A. I don't know.
Q. And by whom?
A. I don't know.
Q. And again, you would rely on Dr. Barnett to advise of all the risks and complications of the procedure and to obtain informed consent concerning those material risks and complications, correct?
A. That's correct.
Q. Any discussion with the family or with Mary Lou

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Zimmerman since this evaluation?
A. Not to my recollection.
Q. When did you first learn that there was a problem or a complication with Mary Lou Zimmerman?
A. When they called me and told me I needed to schedule a deposition.
Q. Is there anything -- let me just have a minute, if you would, please. We're just about done.

- - - -

(Thereupon, a discussion was had off the record.)

- - - -

Q. You list the medications that she was currently taking. Do you know how long she had been on those medications?
A. Not by this evaluation.
Q. Do you know whether there had been any changes in the dosages?
A. Not by this evaluation.
Q. And aside from the Anafranil, do you know of any other medications that she had tried for the OCD, other than what was listed in her current medications?
A. Not by this evaluation.
MR. LINTON: Give us just a few

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minutes. We're just about done.

- - - -

(Thereupon, a discussion was had off the record.]

- - - -

Q. Earlier you outlined a list of is it the SIRs?
A. SSRIs, selective serotonin reuptake inhibitors.
Q. The SSIRs?
MR. MALONE R-I.
MR. RUF R-I.
Q. My mistake. SSRI to treat OCD, and you listed them for us. Are there any other drugs known to you to treat OCD?
A. There are some drugs we use in combination, things like Buspar, Klonopin, which she was on at the time of this evaluation. Almost every drug known to psychiatry has at some time or another been tried.
Q. I'm talking about the ones that you recognize as a treatment modality for OCD.
A. That would be it.
Q. Can these drugs be taken in combination with each other?
A. They can be but typically are not given that way. They're not mors effective in combination.
Q. Do different patients have different success with

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these different drugs?
A. Yes.
Q. For example, one might respond to Prozac, one might not?
A. That's correct.
Q. And if they don't, you move them to the next one on the list?
A. That's correct.
Q. And you keep going back and forth and basically experimenting until you find the right mix that either treats or doesn't treat the OCD?
A. Yes.
Q. Are you aware of, aside from the information under your current medication list, whether Mary Lou Zimmerman underwent trial therapies of any of these drugs?
A. I don't recall.
Q. And if she did for what period of time?
A. That's correct, I don't recall.
Q. This is going to be my last chance to talk to you before this case goes to trial. I want to make sure I have a full understanding of your account of your involvement with Mary Lou Zimmerman. Is there anything else significant in your mind that we haven't covered concerning your evaluation and

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recommendations for Mary Lou Zimmerman?
A. Not that I'm aware of.
Q. Okay. Thank you very much, Dr. Malone.
MR. MALONE: Now, she's going to do a transcript of your deposition, Doctor, and if you just give her the address that you would like her to mail it to, whether it be here at The Cleveland Clinic Foundation or home, she'll send it to you.
THE WITNESS: Here at the Cleveland Clinic, 9500 Euclid Avenue, Desk P, as in Paul, 57, Cleveland, 44195.

DONALD A. MALONE, JR., M.D.

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CERTIFICATE

The State of Ohio) SS:
County of Cuyahdga.)

I, Laura L. Ware, a Notary Public within and for the State of Ohio, do hereby certify that the within-named witness, DONALD A. MALONE, JR., M.D., was by me first duly sworn to testify the truth, the whole truth, and nothing but the truth in the cause aforesaid; that the testimony then given was reduced by me to stenotypy in the presence of said witness, subsequently transcribed into typewriting under my direction, and that the foregoing is a true and correct transcript of the testimony so given as aforesaid.

I do further certify that this deposition was taken at the time and place as specified in the foregoing caption, and that I am not a relative counsel or attorney of either party or otherwide interested in the outcome of phis action.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my seal of office at Cleveland, Ohio, this 30th day of August, 2000.

Laura L. Ware, Ware Reporting Service
21860 Crossbeam Lane, Rocky River, Ohio 44116
My commission expires May 17, 2003.

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H

CURRICULUM VITAE

Donald A. Malone, Jr., M.D.

TITLE:

Staff Psychiatrist
Section Head, Adult Primary Services
Director, Sub-specialty Programs for Mood and Anxiety Disorders
Cleveland Clinic Foundation
Assistant Professor, Department of Psychiatry
Ohio State University

HOME ADDRESS:

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216/444-5817
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MARITAL STATUS:

Married - Jennine A. Malone
Three children

SOCIAL SECURITY NUMBER:

300-62-4443

EDUCATION:

1981	B.S. Youngstown State University Summa Cum Laude
1985	M.D. Northeastern Ohio Universities College of Medicine Alpha Omega Alpha
1995	Graduate Cleveland Clinic Foundation Executive Program in Practice Management

CLINICAL TRAINING & EXPERIENCE:

1985- 1986	PGY-I Internal Medicine Youngstown Hospital Association Youngstown, Ohio

1986- 1988	*Resident in Psychiatry* *Massachusetts General Hospital* *Boston, Massachusetts*
1988 - 1989	*Chief Resident - Acute Psychiatry Service* *Massachusetts General Hospital* *Boston, Massachusetts*

CLINICAL & HOSPITAL SERVICE RESPONSIBILITIES:

1987- 1989	*Associate Clinical Staff* *Pembroke Hospital* *Pembroke, Massachusetts*
1988 - 1989	*Affiliated Staff* *Habit Management Institute* *Boston, Massachusetts*
1989 - 1991	*Associate Staff* *Cteveland Clinic Foundation* *Department of Psychiatry* *Cleveland, Ohio*
1991 - Pnssent	*Staff* *Cleveland Clinic Foundation* *Department **of** Psychiatry* *Cleveland, Ohia*
1990 - Present	*Director, ECT Services* *Department of Psychiatry* *Cleveland Clinic Foundation*
1990 - 1997	*Associate Director* *Residency Training Program* *Department of Psychiatry* *Cleveland Clinic Foundation*
1991 - July, 1998	***Head,** Grand Rounds Committee* *Department of Psychiatry* *Cleveland Clinic Foundation*
1993 - Present	*Director, Sub-special9 Programs for Mood and Anxiety Disorders* *Department of Psychiatry* *Cleveland Clinic Foundation*
1995 - 1997	*Head, Research Committee* *Department of Psychiatry* *Cleveland Clinic Foundation*

1990 - Present	*Member, Research Committee* *Department of Psychiatry* *Cleveland Clinic Foundation*
1996 - Present	*Section Head, Primary Adult Services* *Department of Psychiatry* *Cleveland Clinic Foundation*
4998 - Present	*Consulting Staff, Heather Hili Hospital* *Chardon, Ohio*

ACADEMIC APPOINTMENTS:

1986 - 1989	*Clinical Fellow in Psychiatry* *Harvard Medical School*
1993 - Present	*Assistant Professor, Department of Psychiatry* *Ohio State University*

OFFICER AND COMMITTEE ASSIGNMENTS:

1986- 1989	*Residents' Association Committee* *Massachusetts General Hospital*
1988- 1989	*Residency Training Committee* *Massachusetts General Hospital*
1989 - 1977	*Quality Assurance Committee* *Department of Psychiatry* *Cleveland Clinic Foundation*
1989 - Present	*Head, ECT Subcommittee* *Department of Psychiatry* *Cleveland Clinic Foundation*
1995- 1997	*Head, Research Committee* *Department of Psychiatry* *Cleveland Clinic Foundation*
1990- 1991	*Co-Chairman Scientific Program Committee* *Ohio Psychiatric Association*
1990 - 1991	*Co-Chairman Program Committee* *Cleveland Psychiatric Society*
1991 - 1992	*Chairman Liaison Committee* *Cleveland Psychiatric Society*

1991 - 1992	*Treasurer, Cleveland Consultation Liaison Society*
1992 - 1993	*President: Cleveland Consultation Liaison Society*
1991 - 1994	*Co-Chairman Program Committee* *Ohio Psychiatric Association*
1994 - Present	*Member, Program Committee* *Ohio Psychiatric Association*
1991 - Present	*Training Council* *Association for Convulsive Therapy*
1993 - Present	*Sub-committee on Joint Co-sponsorship of CME* *American Psychiatric Association*
1993	*American Psychiatric Association, Physician Representative* *National Public Education Campaign on Clinical Depression*
1994 - Present	*Long-range Planning Committee* *Ohio Psychiatric Association*
1994 - 1996	*Clinical Roles Committee* *Cleveland Clinic Foundation*
1994 - 1997	*Marketing Committee* *Cleveland Clinic Foundation*
7995 - 1998	*Head, Grand Rounds Committee* *Cleveland Clinic Foundation*
1997 - Present	*Membership Committee* *Ohio Psychiatric Association*
1998 - Present	*Chairman, Membership Committee, OPA*
1997 - Present	*Laughlin Fellowship Selection Committee* *American College of Psychiatrists*
1994 - 1998	*Institutional Review Board* *Cleveland Clinic Foundation*
1998 - Present	*Formulary Sub-committee* *Cleveland Clinic Foundation*
1999 - Present	*Member, Task Force on EC? Certification* *Association for Convulsive Therapy*
1999 - Present	*Education and Research Foundation* *Ohio Psychiatric Association*

OTHER PROFESSIONAL RESPONSIBILITIES:

Examiner: American Board of Psychiatry and Neurology
Editorial Board: Cleveland Clinic Neuroscience Pathways
Reviewer Psychosomatics, The International Journal of Psychiatry in Medicine
Men's Health Advisor Editorial Board, Cleveland Clinic Foundation

Member, Medical Advisory Board, NAMI Metro Cleveland

PROFESSIONAL ORGANIZATIONS:

1980 *Phi Kappa Phi Honor Society*
1985 *American Psychiatric Association*
1985 *Alpha Omega Alpha*
1988 *American Association for the Advancement of Science*
1989 *Academy of Psychosomatic Medicine, Fellow*
1989 *Ohio Psychiatric Association*
1989 *Cleveland Consultation-Liaison Society*
1990 *Cleveland Psychiatric Society*
1990 *American Association of Directors of Psychiatric Residency Training*
1990 *Association for Convulsive Therapy*
1992 *Society for Neuroscience*
1995 *International Society for Sport Psychiatry*
1996 *Member, The American College of Psychiatrists*

HONORS:

1980 *Phi Kappa Phi Honor Society*

1985 *Alpha Omega Alpha*

1988 *Laughlin Fellowship, American College of Psychiatrists*

1993 *Fellow, Academy of Psychosomatic Medicine*

1994 *President's Award, Ohio Psychiatric Association*

1996 *Member, The American College of Psychiatrists*

1996 *President's Award, Ohio Psychiatric Association*

1998 *Fellow, American Psychiatric Association*

CENSURE & CERTIFICATION:

7989 *Ohio Medical License*
Registration No. ***5823****7*
(active)

1991 *ABPN Board Certification in Psychiatry*
Certificate No. 34254

1996 *ABPN Added Qualifications in Geriatric Psychiatry*

TEACHING EXPERIENCE:

High School

1982 - 1983	*Chemistry Teacher* *Upward Bound Program* *Western Reserve Academy* *Hudson, Ohio*

Medical Student Supervision & Teaching

1987- 1989	*Lecturer* *Harvard Medical School Core Seminar Series* *Massachusetts General Hospital*
1988 - 1989	*Acute Psychiatry Service* *Massachusetts General Hospital*
1992 - *Present*	*Lecturer* *Ohio State Medical School Core Seminar Series* *Cleveland Clinic Foundation*
1992 - *Present*	*Supervisor* *Ohio State Medical School Core Clerkship in Psychiatry* *Cleveland Clinic Foundation*

Psychiatry Resident Supervision & Teaching

1988- 1989	*Acute Psychiatry Service* *Massachusetts General Hospital*
1988	*Lecturer, Resident Orientation* *Massachusetts General Hospital*
1989 - *Present*	*Psychotherapy Supervisor* *Cleveland Clinic Foundation*
1989 - *Present*	*Lecturer, Resident Didactic Seminars* *Cleveland Clinic Foundation*
1990 - *Present*	*Clerkship Director, Electroconvulsive Therapy Elective* *Cleveland Clinic Foundation*

1990-1997	*Associate Director* *Psychiatry Residency Training Program* *Cleveland Clinic Foundation*

GRANT SUPPORT:

1990	*"Psychiatric Disorders in Weightlifters Using Anabolic Steroids"* *Cleveland Clinic Foundation Research Grant #3206* *Co-PI with Robert J. Dimeff, M.D.* *Grant award - $20,300.*
1992	*"Anabolic Steroids: A New Issue in Prevention Research"* *National Institute on Drug Abuse (RO1-DA07793)* *Consultant to Paul J. Goldstein, Ph.D.* *Grant award - $1,800,000.*
1994	*"A Clinical Evaluation of Risperdal in the Treatment of Schizophrenia"* *Janssen Research Foundation Protocol #RIS-USA-54* *Co-investigator*

PUBLICATIONS:

Original Publications

7. *Giannini AJ, Nageotte C, Loiselle RH, Malone DA, Price WA: Comparison of chlorpromazine, haloperidol, and pimozide in the treatment of phencyclidine psychosis: DA-2 receptor specificity. Clin Toxicology 1985; 22(6):573-9.*

2. *Malone DA, Wagner RA, Myers JP, Watanakunakorn C: Enterococcal bacteremia in two large community teaching hospitals. Am J of Med 1986; 8l:601-6.*

3. *Giannini AJ, Malone DA, Piotrowski TA: The serotonin irritation syndrome - A new clinical entity? J Clin Psychiatry 1986; 47(1):22-25.*

4. *Giannini AJ, Malone DA, Loiselle RH, Price WA: Treatment of depression in chronic: cocaine and phencyclidine abusers. J Clin Pharmacol 1986; 26:211-4.*

5. *Malone DA, Wagner RA, Myers JP, Watanakunakorn C: Role of appropriate antimicrobial therapy in the outcome of enterococcal bacteremia. Am J Med 1987; 82:1283-4.*

6. *Giannini AJ, Malone DA, Loiselle RH, Price WA: Blunting of TSH response to TRH in chronic cocaine and phencyclidine abusers. J Clin Psychiatry 1987; 48(1):25-26.*

7. *Malone DA, Stern TA: Successful treatment of acquired tourettism and major depression. J Geriatr Psychiatry Neurol 1988: I: 169-170.*

8. Deckert DW, Malone DA: Severe obsessive compulsive disorder. J Clin Psychiatry **1990; 51(6):259.**

9. Malone DA: Tone discrimination secondary to amitriptyline. J Clin Psychopharmacol **1991; 11(3):221-222.**

10. Malone DA, Camara EG, Krug JH: Ophthalmologic effects of psychotropic **medications.** Psychosomatics **1992; 33 (3): 271-277.**

11. Malone DA, Dimeff RJ: The use of fluoxetine in depression associated with anabolic steroid withdrawal: A **case** series. J Clin Psychiatry **1992; 53 (4): 130-132.**

12. Malone DA, Dimeff RJ, Lombardo JA, Sample RHB: Psychiatric-effects and psychoactive substance **use** in anabolic androgenic steroid users. Clin J Sport Med, **1995; 5 (1): 25-31**

13, Muzina DJ, Malone DA: New antidepressants: More options for tailoring treatment. Cleveland Clin J Med, 1996; **63 (7): 406-412.**

14. Block M, Gelenberg AJ, Malone DA: Rational **use** of the newer antidepressants. Patient Care **1997; 31 (6): 49-77.**

15. Muzina DJ, Malone DA: Panic disorder in primary care: Cause of unexplained symptoms. Cleve Clin J Med **1997; 64** (8): **437-443.**

16. Malone DA: Anxiety and depression. Patient Care, **1999; 33** (13): **8-10.**

17. Gajwani P, Malone DA: Fatigue and ahhedonia: Patient care; 33 **(20): 174-175**

Book Chapters and Other Publications

1. Malone DA: The psychiatric effects of medications, in Clinical Preventive Medicine, Matzen RN, **Laiig** R (eds), St. Louis, 1993, Mosby-Year Book, Inc.

2. Malone DA, Sorboro JM: The pharmacology of anabolic androgenic steroids, in Principles of Addiction Medicine, Miller **NS,** Doot MC (eds), Chevy Chase, MD, **1994,** American Society of Addiction Medicine, Inc.

3. Malone DA: Pharmacological therapies of anabolic-androgenic steroid addiction, in Pharmacological Therapies for Drug and Alcohol Addictions, Miller NS, Gold **MS** (eds), New **York, 1995,** Marcel Dekker, Inc.

4. Malone DA (special **issue** medical editor): Anxiety and depression handbook. Patient Care; 33 (IS), **August** 15, 1999.

Book Reviews

1. Stoudemire A., Fogel BS (eds). Principles **of** Medical Psychiatry. Grune and Stratton, Inc. **1907.** Reviewed by Malone, DA. Psychosomatics **1988, 29(4):449-450.**

Abstracts

1. *Malone DA, Wagner RA, Myers JP, Watanakunacorn C: "Enterococcal Bacteremia in Two Large Community Teaching Hospitals"*
American College of Physicians Annual Meeting
Columbus, Ohio
September, 1985

2. *Malone DA, Dimeff RJ: "The Use of Fluoxetine in Depression Associated With Anabolic Steroid Withdrawal"*
Annual Meeting of the Academy of Psychosomatic Medicine
Phoenix, Arizona
November, 1990

3. *Malone DA, Camara EG, Krug JH: "The Ophthalmologic Effects of Psychotropic Medications"*
Annual Meeting of the Academy of Psychosomatic Medicine
Phoenix, Arizona
November, 1990

4. *Malone DA: "The Treatment of Anabolic Steroid Withdrawal Depression"*
Annual Meeting of the Cleveland Consultation-Liaison Society
Cleveland, Ohio
April, 1991

5. *Malone DA, Dimeff RJ, Lombardo J: "The Psychiatric Effects of Anabolic Steroids"*
Annual Meeting of the American Psychiatric Association
New Orleans, Louisiana
May, 1991

6. *Varley JD, Malone DA, Goodkin DE, Fischer J: "The Incidence of Psychiatric Disorders in Patients with Multiple Sclerosis"*
Annual Meeting of the American Psychosomatic Society
*New **York,** New **York***
*April, **1992***

7. *Malone DA, Dimeff RJ: "Anabolic Steroids: Dosage and Psychiatric Effects"*
Annual Meeting of the American Psychiatric Association
Washington, DC
*May, **1992***

8. *Varley JD, Malone DA, Goodkin DE, Fischer J: "Comparison of SCID-Derived Psychiatric Diagnoses and Cranial MRI Data in Patients with Chronic Progressive Multiple Sclerosis"*
***Annual** Meeting of the Cleveland Consultation-Liaison Society*
Cleveland, Ohio
April, 1993

9. *Malone DA, Dimeff RJ: "Psychiatric Symptomatology Associated with Anabolic Steroid Use"*
First International Congress on Hormones, Brain, and Neuropsychopharmacology
Rhodes, Greece
September, 1993

10. *Goodkin DE, Varley JD, Malone DA, et al: "Cranial MRI Lesion Area in Chronic Progressive Multiple Sclerosis (CPMS) Patients are Unrelated to Structured Clinical Interview for DSM-IIIR (SCID) Derived Diagnoses"*
Annual Meeting of the American Neurological Association
Boston, Massachusetts
October, 1993

11. *Adan F, Ivan TM, Malone DA: "Mood States, Perceived Stressors and Residency Training: A Comparison Study of Different Resident Groups"*
Annual Meeting of the American Psychiatric Association
Philadelphia, Pennsylvania
*May, **1994***

12. *Malone DA, Berliner S, Bloomfield E, et al: "The Effect of Hypnotic Agents on ECT-induced Seizure Duration," Neuropsychopharmacolgy, **1994;** 10 (3S): 132S*

13. *Malone DA, Pomelo LJ, Gash JM, et al: "Psychiatric symptoms for breast implant and chronic fatigue patients," 10th Annual Meeting **of** the World Congress **of** Psychiatry, Madrid, Spain, August, 1996*

14. *Baracskay DJ, Malone DA, Paganini EP: "The use **of** psychotropics in hemodialysis," Annual Meeting of the Academy **of** Psychosomatic Medicine, San Antonio, Texas, November, 1996*

ENTATIONS:

Selected Presentations:

*"Cocaine: The Problem **of** Abuse and its Treatment"*
Psychosomatics Conference
Massachusetts General Hospital
Boston, Massachusetts
*October, **1987***

"Acquired Tourettism"
Psychosomatics Conference
Massachusetts General Hospital
Boston, Massachusetts
*November, **1987***

"The Effects of Psychotropics on the Eye and Ear"
Psychosomatics Conference
Massachusetts General Hospital
Boston, Massachusetts
*November, **1987***

"Psychiatric Trauma"
Beverly Hospital Trauma Day
Beverly Hospital
Beverly, Massachusetts
*November, **1988***

"The Psychiatric Aspects of Anabolic Steroid Use"
Department of Psychiatry Grand Rounds
Cleveland Clinic Foundation
Cleveland, Ohio
*May, **1990***

"The Recognition and Treatment of Depression in the Medically Ill"
Visiting Professor
Department of Internal Medicine Grand Rounds
Akron City Hospital
Akron, Ohio
November, 1990

"The Use of Antidepressants in the Medically Ill Patient"
Visiting Professor
Department of Psychiatry Grand Rounds
Timken Mercy Medical Center
Canton, Ohio
*December, **1990***

"Psychiatric Effects of Anabolic Steroid Use"
Department of Psychiatry Grand Rounds
Metro Health Medical Center
Cleveland, Ohio
*February, **1991***

"Psychiatric Effects of Anabolic Steroids in Weightlifters"
Annual Medical Scientific Conference of the American Society of Addiction Medicine
Boston, Massachusetts
*April, **1991***

"Psychiatric Aspects of Anabolic Steroid Use"
Spring Meeting of the Ohio Psychiatric Association
Houston Wood State Park, Ohio
April, 1991

"PsychiatricAspects of Anabolic Steroid Abuse: Dependence and Demographics"
American Society for Pharmacology and Experimental Therapeutics
National Press Club, Washington D.C.
*June, **1991***

"Electroconvulsive Therapy in the 1990's"
Medical Division Grand Rounds
St. Vincent Health Center
Erie, Pennsylvania
March 1992

"Group Therapy in Patients With Borderline Personality Disorder"
Department of Psychiatry Grand Rounds
Cleveland Clinic Foundation
Cleveland, Ohio
April, 1992

"Panic Disorder and Other Related Diagnoses"
Ohio Permanente Medical Group, Inc.
Cleveland, Ohio
July, 1992

"Medical Topics Relevant to Psychiatry"
Laurelwood Hospital
Willoughby, Ohio
November, 1992

"The Psychiatric Effects of Anabolic Steroids"
Visiting Professor, Department of Psychiatry Grand Rounds
West Virginia School of Medicine
Morgantown, West Virginia
April, 1993

"The Psychological Effects of Anabolic Steroids"
Third International Congress of Therapeutic Drug Monitoring and Clinical Toxicology
Philadelphia, Pennsylvania
May, 1993

"Panic and Depression in the Elderly"
The Cutting Edge: Depression and Panic Disorder
Cleveland, Ohio
September, 1993

"Training and Accreditation in ECT"
Annual Meeting of the AADPRT
New Orleans, Louisiana
January, 1994

"The Training and Credentialing of Residents in ECT"
Annual Meeting of the Association for Academic Psychiatry
Tucson, Arizona
March, 1994

"Treatment of Depression - Indications and Outcomes, Short- and Long-term - Where Am We?"
Pittsburgh Psychiatric Society
Pittsburgh, Pennsylvania
September, 1994

"New Developments in-the Treatment of Depression"
Clinton Valley Center Psychiatric Hospital
Bloomfield Hills, Michigan
September, 1994

"The Treatment of Depression in the Medically Ill"
St. Alphonsus Regional Medical Center Grand Rounds
Boise, Idaho
February, 1995

"An Update on OCD"
Rockford Memorial Hospitals Annual Psychiatric Update Day
Rockford, Illinois
March, 1995

"The Anxious Afhlete"
2nd Annual Ohio Sports Medicine Conference
Cleveland Clinic Foundation
Cleveland, Ohio
May, 1995

"Psychopharmacology Update on Anxiety Disorders"
Anxiety and Somatiform Disorders in Children and Adults
Cleveland Clinic Foundation
Cleveland, Ohio
September, 1995

"Psychotropic Drug Use in-the Medically Ill"
5th District Academy of Osteopathic Physicians Meeting
Sandusky, Ohio
October, 1995

"An Update on the Treatment of OCD"
Milwaukee V.A. Hospital Grand Rounds
Milwaukee, Wisconsin
December, 1995

"Training in ECT"
Annual Meeting of the American Association of Psychiatric Residency Training Directors
San Francisco, California
January, 1996

"Anabolic Steroid Use in Adolescents"
Annual Meeting of the American Osteopathic Association
Las Vegas, Nevada
October, 1996

"The ECT Workup"
Workshop Director and Presenter
Annual Meeting of the American Academy of Psychosomatic Medicine
San Antonio, Texas
November, 1996

"OCD and the Spectrum Disorders"
Texas School of Osteopathic Medicine Grand Rounds
Fort Worth, Texas
December, 1996

"Diagnostic and Treatment Options for Anxiety Disorders"
Kalamazoo Psychiatric Institute Grand Rounds
Kalamazoo, Michigan
June, 1997

"An Update on Atypical Neuroleptics"
Columbia Mercy Medical Center Conference on Clinical Issues in Schizophrenia
Canton, Ohio
November, 1997

"The Spectrum of Obsessive-compulsive Disorders"
International Latino Psychiatric Association Meeting
Chicago, Illinois
May, 1998

"An Update on Panic Disorder"
The Menninger Clinic Course on New Developments in the Treatment of Anxiety Disorders
St. Louis, Missouri
June, 1998

"An Update on Social Anxiety Disorder"
Wright State University College of Medicine Grand Rounds
Dayton, Ohio
February, 1999

"An Overview of Obsessive-compulsive Disorder"
Obsessive-compulsive Disorder Conference, sponsored by NAMI
Cleveland, Ohio
May, 1999

"The Treatment of Depression in Primary Care"
Alpena Hospital Internal Medicine Grand Rounds
Alpena, Michigan
June, 1999

"The Diagnosis and Treatment of Social Phobia"
St. Joseph Hospital Grand Rounds
Youngstown, Ohio
June, 1999

"An Overview of Social Phobia"
Forum Hospitals 5th Annual Behavioral Medicine Conference
Youngstown, Ohio
September, 1999

"The Treatment of Mood Disorders"
Meeting of the Northeast Ohio Academy of Pharmacists
Cleveland, Ohio
October, 1999

"The Diagnosis and Treatment of Panic Disorder"
Fairview Hospital Family Medicine Grand Rounds
Fairview, Ohio
October, 1999

"Obsessive-compulsive Disorder in the Workplace"
Northern Ohio Chapter of the International Employee Assistance Professionals Association
Cleveland, Ohio
November, 1999

Rev. 1/2000

PSYCHIATRIC EVALUATION

MARY ZIMMERMAN
#2744-838-0
August 31,1998

IDENTIFYING DATA: Mary Zimmerman is a 58 year old married white female from Kansas, who is self-referred for evaluation for possible cingulotomy. Information was taken from extensive records from her psychiatrist; the Menninger Institute, as well as the history of her husband.

CHIEF COMPLAINT: "I just can't get over this."

HISTORY OF PRESENT ILLNESS: This is one of many formal psychiatric evaluations for this 58 year old married white female who has had a history of obsessive-compulsive symptoms since around the age of 28. This was during *her* pregnancy with her third child. She states it began on an occasion where she cut her leg shaving, and then began to feel "dirty," She began to then clean her legs excessively, and this spread to other areas of her body. She was always a clean and neat person prior *to* that, but never excessively so. Symptoms then worsened after the delivery of her child. This was very problematic in that she had great difficulty in changing diapers, and would never be able to return to anyplace in the home when? the baby had thrown up or a diaper had been changed. She began to clean the house extensively, *and* would find herself washing laundry many hours a day. Eventually it progressed to the point where she could not be touched by others, and in fact, could not shake my hand prior to this appointment The symptoms have improved at times over the years, but have always been present, and essentially have worsened over the past 30 years. They are at the point now where she is no longer able to work. She has been on disability for the past three years. This has been very upsetting to her.

She does feel depressed much of the time, though the depression itself is not severe. She has difficulty concentrating, and her motivation is significantly impaired. There is a significant decrease in her energy level versus what it should be. She denies ever having any hallucinations, paranoia, or manic symptoms. On occasion she will be able to go out of the house and do things; however, it *is quite difficult* for her, For example, if the car would run over something dirty in *the* street, the car would then be contaminated, and she would require a great deal of time before riding in it again. She denies any other symptoms of OCD, including checking behaviors, fear of harm *to* others, or other compulsive behaviors.

PAST PSYCHIATRIC HISTORY: She has an extensive psychiatric history over the past 30 yeas. She has been seeing Dr. Donelly in Kansas for the past 10 years. During *that* period she has also been to the Menninger Institute for several inpatient hospitalizations. She has been hospitalized many 'rimes over the years. Her first hospitalization was for a several-month period after the birth of her third child. She has been on multiple medication regimens which are well documented in her old records. There are essentially no medications which may be effective fur OCD, or combinations of medications which have not been tried. In addition to the medications she has had extensive cognitive behavioral, as well as supportive psychotherapy over the years. Apparently the cognitive behavioral therapy has been very frustrating to both she and the therapist

because of her inability to confront her fears. She states that the best medication overall was Anafranil. though it provided rather limited benefit. She also had sexual dysfunction and some bladder incontinence with the Anafranil which limited its use.

She denies drinking alcohol or using illicit drugs, She does not smoke tobacco. She uses caffeine oniy moderately.

PAST MEDICAL HISTORY: This is significant for hypertension, hypercholesterolemia, a tubal ligation, and a diagnosis of grand mal epilepsy, Apparently she has had two seizures over the years, and currently is on Tegretol for this.

MEDICATIONS: Klonopin, 0.5 mg. p.o. q. day Neurontin, 300 mg. p.o. q.i.d.; Prozac, *80* mg. p.o. q. day; Atenolol, 100 mg. p.o. q. day; Zyprexa, 5 mg. p.o. q.h.s.; Tegretol, 200 mg. p.o. t...d ; Prinivil, 40 mg. p.o. q. day; and Premarin, 0.625 mg. p.o. q. day

ALLERGIES! No known drug allergies

FAMILY PSYCHIATRIC HISTORY: This is significant for depression in both her father and sister. She also has a brother who suffered from alcoholism.

SOCIAL HISTORY: The patient has been married fur *the past* 40 years to her first and only husband, Togetherthey have three children. She has a daughter who still lives in town, and two other children who live out *of* *town.*

She *is* the youngest *of* four siblings. She had one sister who died,

The patient worked up until approximately three years ago, She was an *accountant* end apparently was very proud of the work that she was able *to* do. Her obsessive-compulsive symptoms began to interfere substantially with her work over the years, and according to her husband "they kept her an much longer then they really should have." She became most tearful when she was discussing her need to be on disability.

MENTAL STATUS EXAMINATION: The patient is a pleasant white female who was casually dressed and groomed. She was able to provide an adequate history for most things;though-did count on her husband to help out on occasion. Her affect throughout much *of* the interview appeared sad, and she was tearful at various times. Her speech was *of* a normal rate and tone. Her mood was described as "dawn and frustrated." Cognition was grossly intact. She was oriented *to* person, place, and time. She was able to recall three objects immediately, but only ane out of three after *five* minutes time. She did not have the motivation to calculate serial 7's or *to* perform spelling tasks. There was no current evidence of any delusions, hallucinations, or paranoia. She denied all suicidal or homicidal ideation, although she has had some suicidal ideation in the past. Her insight and judge-ment overall were fait.

IMPRESSION: This is a *58* year old married white female with *a* long history of obsessive-compulsive disorder which is severe. She was administered a YBOCS, and scored 38 out of 40. She has been treated with essentially all known therapeutic interventions for obsessive-compulsive disorder with regard to psychotherapy and medication management. Her records from the Menninger Institute, as well as her current psychiatrist, are extensive and inclusive. It *is* my opinion that it is unlikely to be any combination of medications or single medication that would be effective for her that hasn't already been tied. It is the opinion *of* her psychiatrist, ana I would

concur, that cingulotomy is a reasonable option for the treatment of her severe treatment-resistant obsessive-compulsive disorder.

I discussed the potential risks and benefits from a psychiatric perspective of a cingulotomy with both her and her husband. They are scheduled to meet with Dr. Barnett later today and discuss the potential surgical risks. They will then decide on whether to proceed with the cingulotomy procedure.

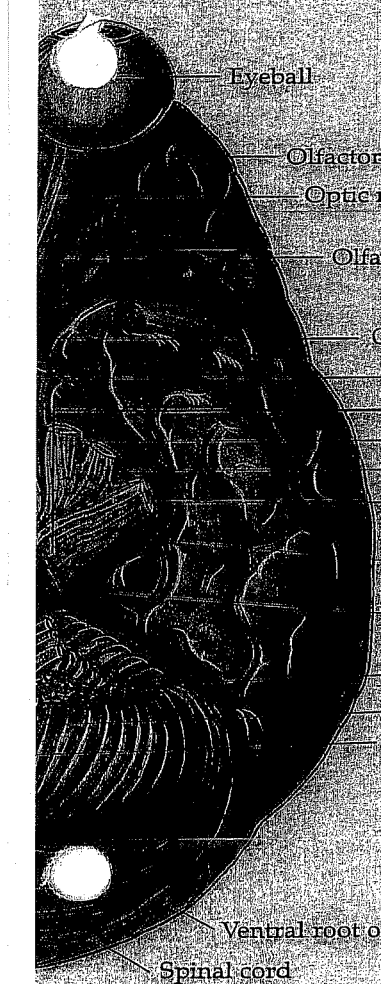
DIAGNOSES:

Axis I:	Obsessive-compulsive disorder, severe
Axis II:	Deferred
Axis III:	Hypertension, hypercholesterolemia, epilepsy
Axis IV:	Mild family stressors
Axis V:	40

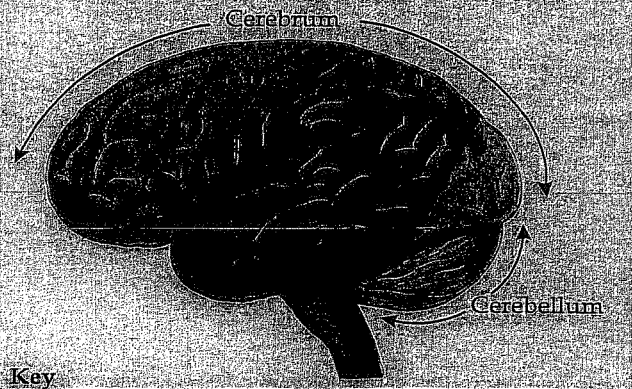
TREATMENT PLAN: As noted, the patient will return to her psychiatrist in Kansas. She will see Dr. Barnett here to discuss the risks and potential benefits of cingulotomy. If she and her husband decide on cingulotomy, they will re-contact us and come back to Cleveland for the procedure.

Donald A. Malone, Jr., M.D.

in



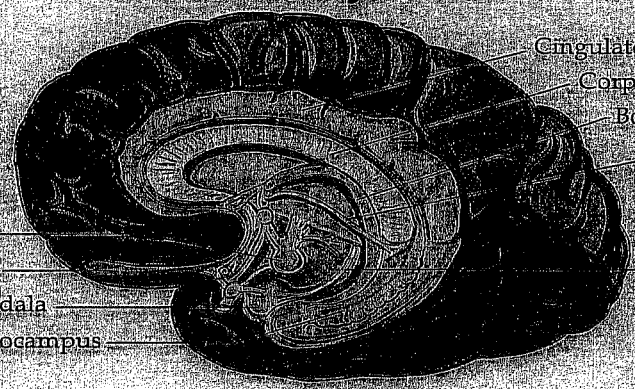
Lobes of the Brain



Key

- Frontal lobe
- Parietal lobe
- Temporal lobe
- Occipital lobe

Limbic System



PLAINTIFF'S EXHIBIT
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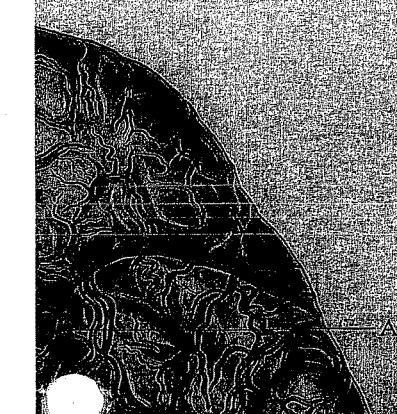
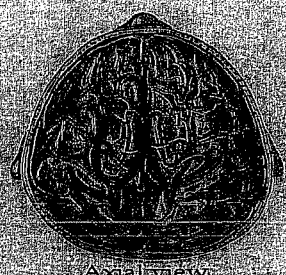
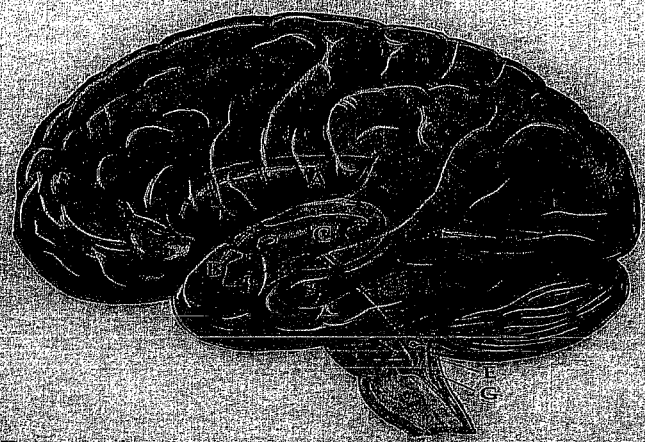




Ventricles of the Brain

(lateral view)



Key

A) Lateral ventricle
1-Anterior horn
2-Posterior horn
3-Inferior horn
B) Interventricular foramen (Monro)
C) Third ventricle
D) Cerebral aqueduct
E) Fourth ventricle
F) Lateral apertures (Luschka)
G) Median aperture (Magendie)

Treatment of Psychiatric Illness by Stereotactic Cingulotomy

H. Thomas Ballantine, Jr., Anthony J. Bouckoms, Elizabeth K. Thomas, and Ida E. Giriunas

The treatment of 198 psychiatrically disabled patients with stereotactic cingulotomy was evaluated prospectively for a mean follow-up of 8.6 years. Patients with major affective disorders and anxiety disorders fared the best, with a return to normal functioning in the majority. Patients with obsessive-compulsive disorders, schizophrenia, and personality disorders improved less predictably, with an uneven improvement in functioning that required active ongoing psychiatric treatment. Low mortality and morbidity, a reduction of violent behavior, a possible reduction of suicidal risk, and a lessening of the intractable suffering of chronic psychiatric illness all indicate that cingulotomy can be an effective, safe treatment for patients with affective disorders that are unresponsive to all other forms of therapy.

Introduction

On April 4, 1962, we began a study of the safety, efficacy, and appropriateness of bilateral anterior stereotactic cingulotomy for the treatment of patients whose psychiatric illnesses or chronic pain had been refractory to all other treatments. As of January 1, 1986, 465 patients had been operated on, and 696 separate bilateral cingulate interruptions had been performed.

Respite this extensive experience (Ballantine et al. 1967, 1972, 1977, 1985), a detailed descriptive analysis of this group of patients had not been previously reported, nor were predictors of outcome satisfactorily identified in previous publications. To overcome this deficiency, we have undertaken a detailed analysis of a cohort of 198 psychiatric patients operated on during the first 20 years of this study.

In this article we report on the relative safety of the procedure, the diagnostic profile of the operated patients, and the relationship of the type of psychiatric illness to status postcingulotomy. The relationships of postcingulotomy status to the sex of the patient, number of operations, and duration of follow-up will be presented in a subsequent paper.

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Received August 29, 1986; revised December 1, 1986.

0006-3223/87/$03.50

Methods

Subjects

This report is limited to a study sample of 198 psychiatric patients drawn from a population of 387 individuals who had one or more cingulate interruptions for the treatment of psychiatric illness or chronic pain during the years 1962 to 1982. All were 2–22 years postoperative at the time of evaluation. Psychiatric patients comprised 70% of this group (n = 273), whereas 21% carried diagnoses of "chronic pain syndrome" and 9% suffered from the intractable pain of terminal cancer. The pain patients will be reported separately. The psychiatric patients were referred by their treating psychiatrists because psychotherapy, pharmacotherapy, and electroconvulsive therapy (ECT), when indicated, had failed. A three-person Institutional Review Board (IRB), consisting of the operating neurosurgeon, a psychiatrist, and a neurologist appointed by the General Executive Committee of the Massachusetts General Hospital, assessed the suitability of each individual for inclusion in this series, based on diagnosis and prior treatment. Cingulotomy was recommended only if the IRB concluded unanimously that all reasonable nonoperative treatments had failed, that informed consent for surgery had been obtained, and that the patient might benefit from the operation.

Psychiatric Diagnosis

The formal criteria for psychiatric diagnoses have changed over the years from the introduction of the *Diagnostic and Statistical Manual for Mental Disorders* (DSM-I) in 1951 to DSM-II (1968) and now DSM-III (1979). The patients seen during the early years of the study were therefore diagnosed by different criteria from those seen since 1979. Fortunately, the criteria for the major psychiatric diagnoses of depression and schizophrenia have changed little over the years, allowing the older DSM-I and DSM-II diagnoses to be classified according to DSM-III. Consequently, all patients in this study had their principal diagnoses designated by modern DSM-III criteria.

Operative Technique

Through bilateral burr holes, 1.2 cm in diameter, 9.5 cm posterior to the nasion, and 1.5 cm to either side of the midline, electrically insulated thermistor electrodes are positioned in each cingulate bundle under fluoroscopic control following ventriculography. The targets are located 0.66 cm lateral to the midline bilaterally. Anteroposteriorly, the targets vary symmetrically from 0 cm to 4 cm posterior to the anterior horns of the lateral cerebral ventricles.

The uninsulated 1.0-cm tips of the electrodes are heated to 80–85°C for 100 sec by a radiofrequency current. The lesions are calculated to be 1.0 cm in diameter and 2.0 cm in vertical length. The lower limits are 1.0 mm above the roof of the ventricles, as seen radiologically.

Data Collection and Analysis

Adequate follow-up data were available on 198 of 273 psychiatric patients (73%). These included questionnaires, a detailed review of the clinical histories, and long-term outpatient contacts with many of the study group. On the basis of this cumulative information, a DSM-III classification was confirmed, and each subject's level of social functioning

Results

and wellness was determined according to the rating scale described below. Demographic variables of sex, age at time of first operation, number of years ill, referring and consulting diagnoses, number of procedures, course following procedures, and complications were recorded for simple and multivariate analyses relative to each patient's postoperative status.

Earlier reports of our experience with stereotactic cingulotomy employed a 0–5 categorical-rating scale to-designate a patient's current, global, psychiatric–social status. To maintain continuity and comparability to those studies, this scale was maintained as the central classifying criterion:

Status 5. Patient is essentially well, functioning normally without treatment of any kind.
Status 4. Patient is functionally normal on maintenance medication and/or psychotherapy.
Status 3. Patient is considerably improved over preoperative state, no longer critically ill or institutionalized, usually working to some extent, but still displays many serious problems or suffers periodic recurrence of disabling symptoms, requiring continuing psychiatric supervision.
Status 2. Patient shows slight improvement and better response to treatment, but still requires intensive care and is unabie to work.
Status 1. Patient shows no change—neither improvement nor decompensation.
Status 0. Patient's illness has progressed; symptoms are worse; he is unable to function as well as before cingulotomy.
Status S. Suicide, which may occur in any of the above statuses.

All patients accepted for cingulotomy were completely disabled or severely handicapped and were unresponsive to all reasonable and generally accepted nonoperative therapy. The determination of postoperative status required the concurrence of all investigators.

Results

Safety

There have been no deaths in this series of 696 cingulotomies. Two hemiplegias were the result of intracerebral hematomas provoked by insertion of the ventricular needles: an incidence of 0.03%. Postoperative seizures, well controlled by phenytoin, occurred in 1% of the patients.

An ongoing independent study of a *cohort* of our patients is being performed for the federal government by the Department of Psychology, Massachusetts Institute of Technology. The preliminary reports state: (1) there is currently no evidence of lasting neurological or behavioral deficits after surgery; (2) a comparison of preoperative and postoperative scores reveals significant gains in the Wechsler IQ ratings; and (3) when the total group of patients was subdivided according to diagnosis, the incidence of improvement was high in patients with persistent pain and also in those with depression, but low in those with a diagnosis of schizophrenia or obsessive-compulsive neurosis. The only decrement identified by these investigators was an irreversible decrease in performance of the Taylor Complex Figure Test in patients over the age of 40 (Corkin et ai. 1979; Corkin and Hebben 1981) {Figure 1).

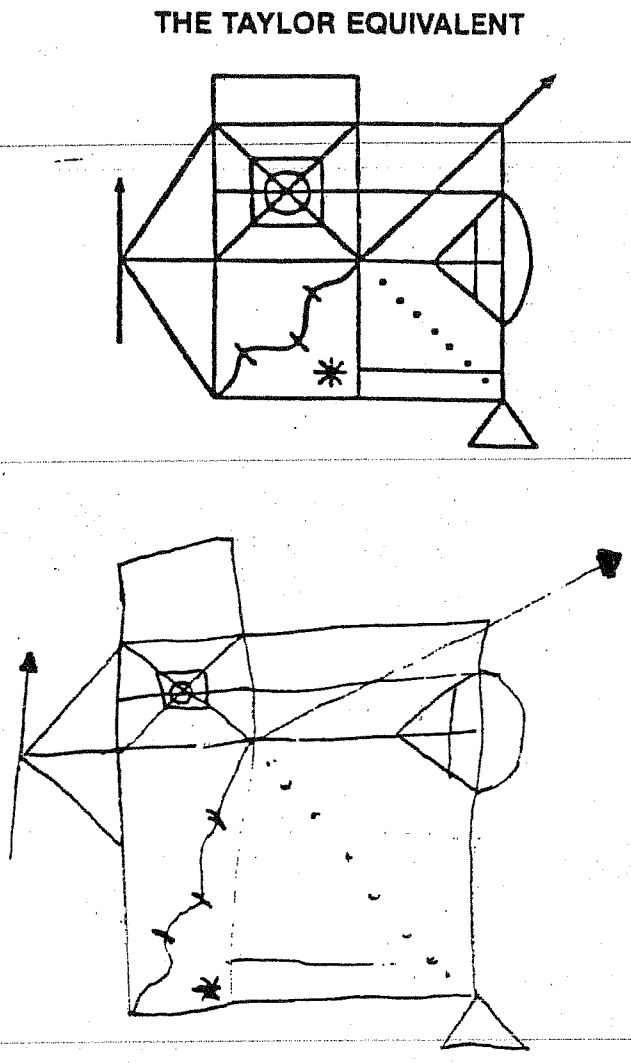


Figure 1. Example of decrease in performance of the Taylor Complex Figure Drawing. (top) The model. (bottom) The patient's drawing postoperatively.

Patient Characteristics

There are 111 women (56%) and 87 (44%) men in the study population of 198. The mean age at the time of first cingulate interruption is 39.3 years (range 10–75 years). The mean postoperative follow-up time is 8.6 years, ranging from 2 years to 22 years following the first cingulate procedure. Distribution by primary diagnosis is shown in Table 1.

Changes in Psychiatric Status after Cingulotomy

The preoperative seventy of the 198 patients' illnesses and disability was extreme. A marked depressive component was universally present, and 43% (n = 86) were suicidal, with 26% (n = 52) attempts and 17% (n = 34) ideation. The postoperative follow-up status is shown in the distribution chart, with the best at the left (Figure 2). Twenty-six patients (13%) are fully recovered and stable (status 5) without recourse to ongoing

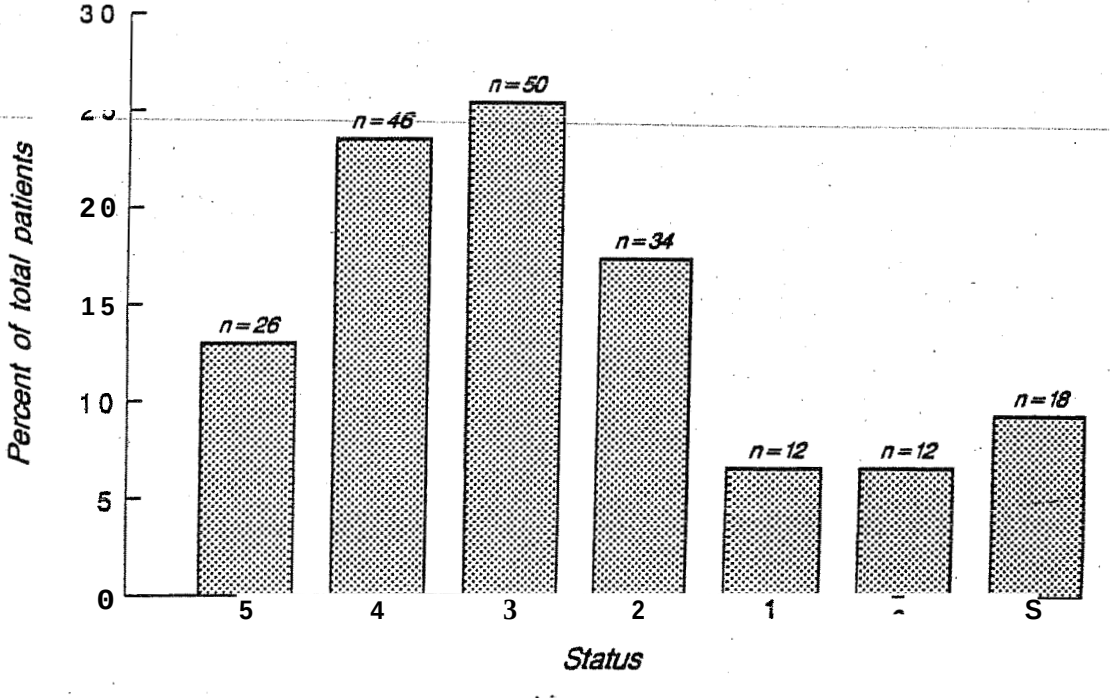
Table 1. Diagnostic Distribution of 198 Psychiatric Patients

	n	
Affective disorders	120	(61%)
Unipolar	83	
Bipolar	23	
Schizoaffective	14	
Obsessive-compulsive	32	(16%)
Anxiety	14	(07%)
Schizophrenia	11	(06%)
Personality disorders	9	(04%)
Miscellaneous	12	(06%)
Atypical psychosis	3	
Uncertain diagnosis	2	
Organic brain syndrome	2	
Violent autistic/MR	2	
Anorexia nervosa	3	

psychiatric treatments. Another 46 patients (23%) continue to need psychiatric supervision and medication, but otherwise are functioning normally (status 4). An additional 51 patients (26%) have varying degrees of psychiatric disability, requiring ongoing supervision and treatment (status 3). Nevertheless, they are markedly improved over their preoperative status. Two illustrative case histories follow.

J.S. is a 34-year-old man who is currently employed as an investigator in the office of a county district attorney. He received the first of two cingulotomies on **May 1, 1978** at the age of 26. His illness began with paranoid thoughts at the age of 18. **Six** months

Figure 2. Postoperative status of 198 psychiatric patients.



after the onset of these symptoms, he assaulted his mother and began psychiatric treatment. The patient was hospitalized at this time, treated with thorazine, and went into remission. One year later, he suffered a second psychotic break, with bizarre and assaultive behavior. ECT and neuroleptic medications brought about another remission, but serious suicidal thoughts at age-20 required hospitalization, lithium, neuroleptics, and ECT, which provided only temporary benefit. Multiple suicidal and homicidal threats continued in spite of long-term hospitalization and therapy. At the time of his first stereotactic cingulotomy, he was labled "schizophrenic" and was not employable.

Postoperatively, J.S. felt more relaxed and better able to concentrate. He enjoyed family life and home projects and was able to complete one college course with a good grade. Ten weeks after cingulotomy, he had another psychotic break that progressed in severity despite massive doses of neuroleptics and lithium.

Repeat cingulotomy was performed in December 1978. This was followed by continual improvement. The patient-was able to return to work and take-two more college courses during the following 10 months. At this point, his father became seriously ill, which disturbed the patient to the point where he admitted himself to a hospital. After 1 week of hospitalization, he was able to go back to school and back to work,

Gradual improvement continued, although the patient required significant psychiatric outpatient supervision. At the age of 33, 7 years after the last cingulotomy, J.S. had graduated from college, was holding a responsible job, and was coaching hockey in his hometown school. A year later, he had progressed to living in his own apartment and had continued to work regularly. However, in an attempt to become independent of his psychiatrist, the patient reduced his medication and suffered a hypomanic attack. This episode was short-lived, and at this writing, J.S. remains gainfully employed.

Because of the need for frequent psychiatric treatment, J.S. is currently considered to be in status 3.

N.A. is a 53-year-old housewife and businesswoman who had a cingulotomy performed when she was 45. She had suffered from a chronic recurrent affective disorder for approximately 20 years. Her symptoms included multiple episodes of depression, somnolence, ataxia, dysarthria, and suspected manic episodes. She had nor responded to ECT, neuroleptics, tricyclic antidepressants, lithium carbonate, monoamine oxidase (MAO) inhibitors, individual milieu, or group or couple therapy. She had made three suicide attempts—two by drug overdoses and one by wrist cutting. The last suicide attempt led to psychiatric hospitalization from March 17 to May 23, 1979, at the end of which time she was referred for cingulotomy.

Over the next 3 months after surgery, there were short bouts of depression without suicidal ideation. Three years after the operation, the patient wrote as follows: "It is hard to believe that yesterday was my third re-birthday—three years since your cingulotomy operation on me. It has been three beautiful years—three years of being able to enjoy life—three years of being able to function as a human being again—being able to be a loving wife, mother, grandmother and friend."

On November 16, 1986, 7.5 years after her cingulotomy, the patient wrote in part:

> On June 29, 1979, a very important day in my life, I was one of the priviledged few to have the cingulotomy operation. I celebrate this date yearly as my re-birthday.
>
> For many, many years before this day, I was plagued with severe depression and was in and out of mental wards and hospitals many, many times. There was no apparent reason for my being depressed. I had taken many different kinds of medication, therapy and shock

treatment—none of which had lasting good results. Many, many times I was not much more than a vegetable—merely existing—not really living—a burden to my family.

During the eight and a half years [sic] since I had the cingulotomy operation, I have been able to lead an active, useful, productive, happy life. . . .

I have compiled figures on my medical expenses for the eight months prior to my cingulotomy operation and for the first eight months of 1986 (these values are shown in Table 2).

The patient is currently being maintained on 150 mg of maprotiline (Ludiomil) daily. She is classified as status 4, in that she is leading a "normal" life, but is still in need of medication.

The remaining 75 patients have had an unsatisfactory outcome: 34 (17%) are only slightly improved (status 2); 12 (06%) are unchanged (status 1); 11 (06%) have deteriorated (status 0) due to progression of the psychiatric illness or a neurosurgical complication (2 patients), and 18 (9%) were suicides.

Psychiatric Diagnoses and Response to Cingulotomy

The question of primary concern is which psychiatric illnesses respond favorably to bilateral stereotactic cingulotomy. To this end, we made a distributional comparison of the postoperative response of subjects in the following diagnostic classifications.

Affective Disorders and Major Depression. Sixty-one percent of the study population carry diagnoses of major affective disorders (n = 120), including unipolar (n = 83), bipolar (n = 23), and schizoaffective (n = 14). There is no significant difference between the subtypes in response to cingulotomy.

The higher degree of favorable response to cingulotomy among the 120 subjects with affective disorders is shown in Figure 3. In comparison to the population as a whole, there is a higher percentage in categories 5 and 4 and a lower percentage in all other categories. However, it is also true that the majority of suicides in the study population (14 of 18) are from this diagnostic group,

Anxiety Disorders. Forty-six patients, 23% of the study group, suffered from anxiety disorders. Thirty-two had an obsessive-compulsive illness, and because of the particular interest in the postoperative status of this diagnostic group (Kelly 1980), we considered them separately and in contrast to 14 subjects with nonobsessive anxiety disorders, e.g., phobic anxiety and generalized anxiety. A clinically noteworthy difference exists between obsessive and nonobsessive anxiety disorders following cingulotorny.

Table 2. Medical Expenses before Operation and for the First 8 Months of 1986

	11/1/78–6/28/79	1/1/86–8/31/86
Hospital	11,697.80	0.00
Psychiatrists	4,753.00	65.00
Other physicians	639.00	52.00
Medications	424.00	408.00
Lab	981.00	63.00
Total	$18,494.80	$588.00

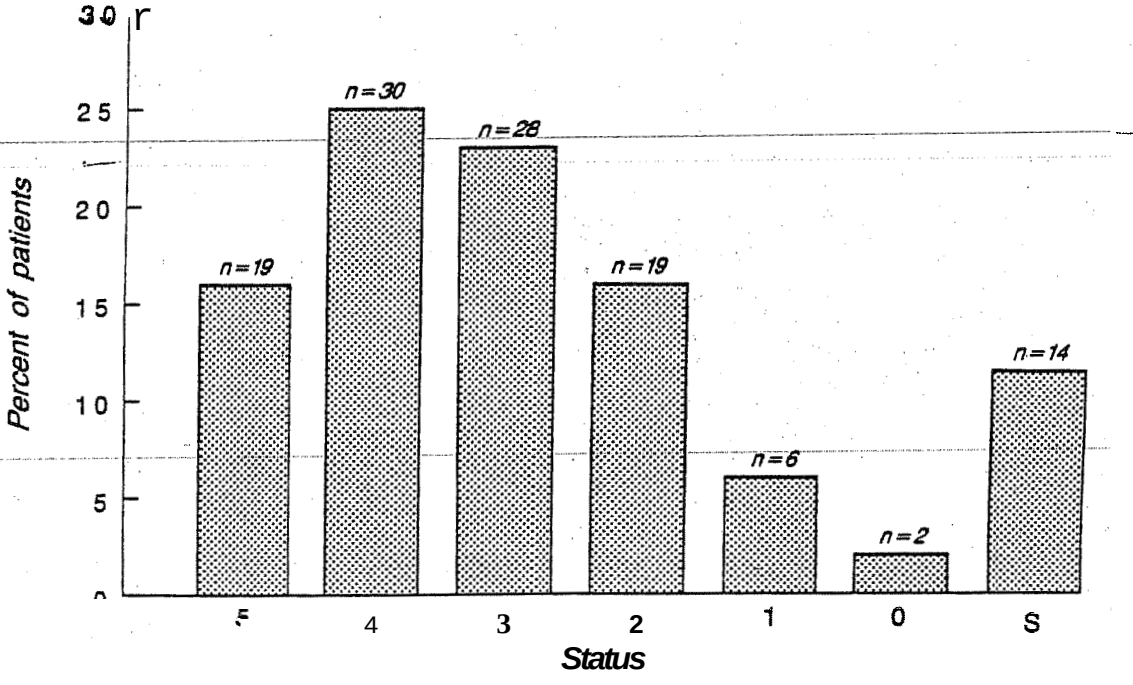


Figure 3. Postoperative status of 120 patients with affective disorders.

Eleven of the 14 anxiety patients have achieved stable marked improvement or functional wellness: 50% (n = 7) are in status 5 or 4 and 29% (n = 4) are in status 3 (Figure 4). In contrast, patients with obsessive-compulsive disorders show a more even distribution across postoperative statuses: 25% (n = 8) are functionally well (status 5 and 4), 31% (n = 10) show marked improvement (status 3), and 41% (n = 14) show slight or no improvement (status 2, 1, 0). Figure 4 contrasts the subtype distributions. The percentages for the combined anxiety disorders are shown in each status for comparison with the total population.

In this study, we find that subjects with obsessive-compulsive disorders do not appear to respond to cingulotomy as dramatically as do those with generalized anxiety or affective disorders.

Schizophrenia. Schizophrenics constitute only 5% of the psychiatric study population (n = 11, 3 women and 8 men). Three of the 11 patients demonstrated negligible or no remission in the course of their disease. Four others, however, experienced considerable improvement. Two of the four are functionally well in status 4 and are employed full time; the other two are in status 3. Another four were violent or self-mutilating, and the alleviation of this behavior is notable. The postoperative status of this small diagnostic group is shown in Figure 5, together with the small sample of personality disorders.

Personality Disorders. A principal diagnosis of personality disorder, unspecified for type in this study, occurs in only nine subjects, and all have additional complex combinations of severe affective and medical problems as well. Primary personality disorders are only 4.5% of the study population. The postoperative status for this diagnostic group

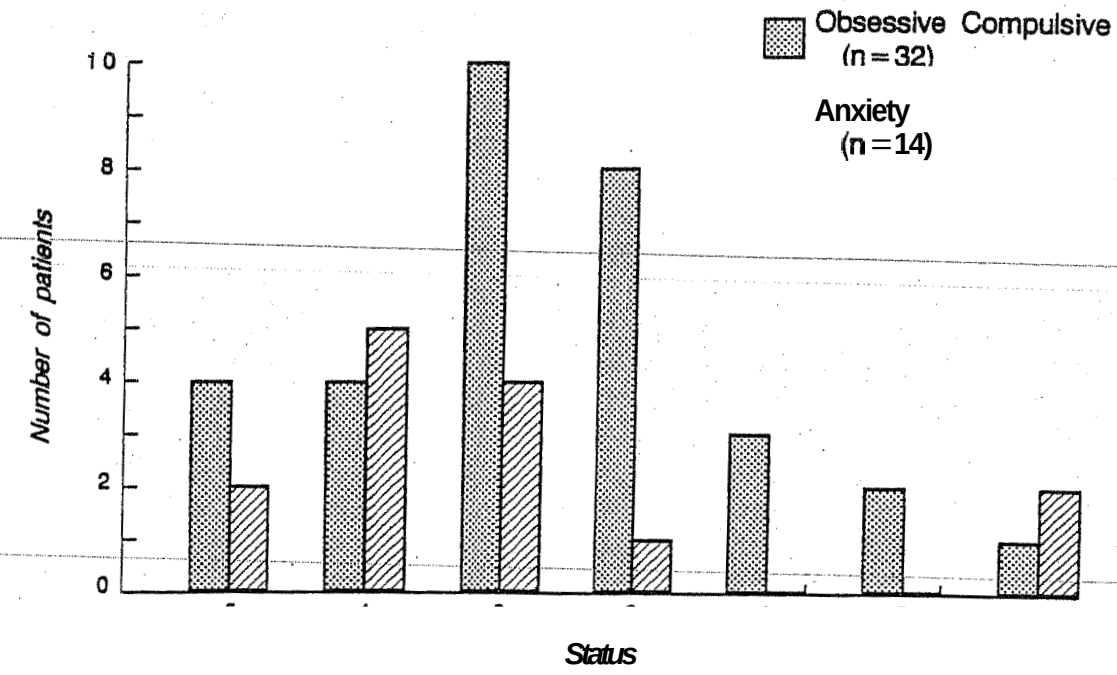


Figure 4. Status postcingulotomy: anxiety **versus obsessive-compulsive disorders.**

is shown in Figure **5.** Axis II personality disorders, in addition to the principal Axis I diagnosis, are a complicating factor in 13% of our 198 cases.

Miscellaneous Psychiatric ***Disorders.*** Twelve subjects with a variety of uncertain, atypical, and unrelated psychiatric disorders were **part** of this series (see Table 1). Three women with severe depression and a principal diagnosis of anorexia nervosa are, after much instability postoperatively, now in status 5 (n = 1) and status 4 **(n = 2).** Two of three subjects with atypical psychosis are status **4;** the other is status 0. Two women with organic brain syndrome are status 0. Two subjects, one man and one woman, with uncertain diagnoses are in status 3 and status 1, respectively. Two retarded, autistic teenage boys are in status 3 and **2;** but in both cases, their improved behavior has allowed them to remain at home and attend a special school.

Lack of cohesiveness among these individuals makes it impossible to generalize about outcome versus diagnosis.

Discussion

Relative Safety of Stereotactic Cingulotomy

The absence of operative mortality and the **low** incidence of serious complications (0.03% hemiplegias and 1% controllable seizure disorders) in a series of 696 bilateral cingulotomies represent firm evidence of the safety of this procedure. Although intracerebral hematomas cannot always be prevented, the sequelae can be readily controlled, provided that recognition and treatment are instituted in a timely fashion. There is also no evidence of diminution in intellectual function, "emotional tone," or "social control." These fa-

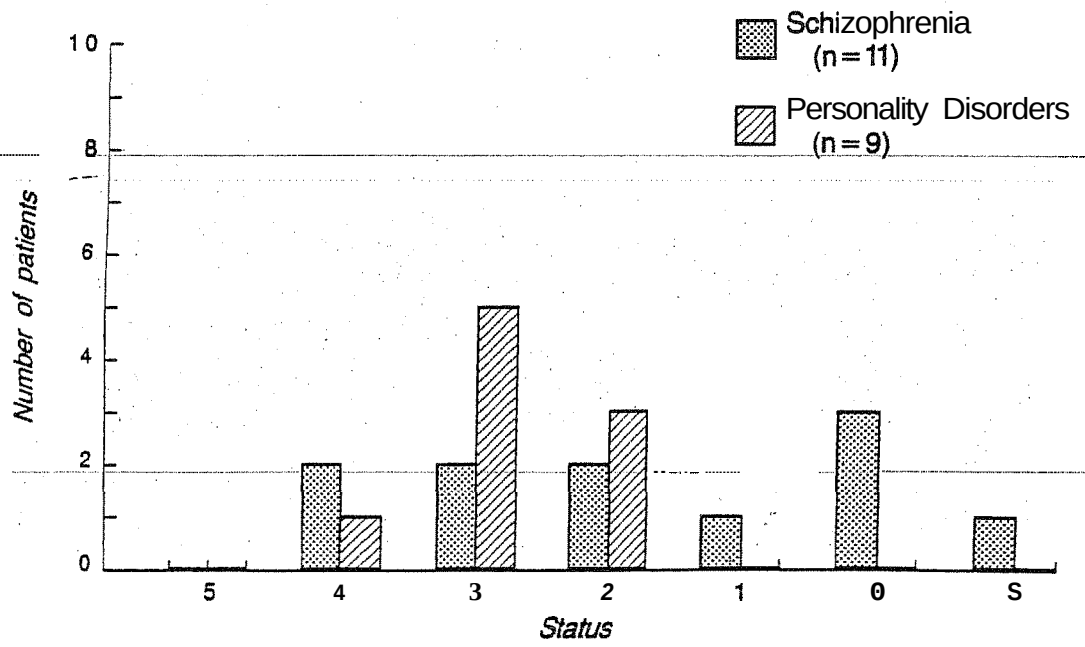


Figure 5. Postoperative status of 11 schizophrenic patients and 9 personality disorder patients.

vorable findings contrast sharply with the complications reported for other types of surgery for psychiatric illness (Tooth and Newton 1961; Tucker 1961; Strom-Olsen and Carlisle 1971; Scoville and Bettis 1977).

Although 45% of our patients needed repeat cingulate interruptions, we have been reluctant to perform two of our standard cingulotomies at the first operation for two reasons. First, a significant number of our patients have required only one operation. Second, "staging" the procedures when more than one is necessary is, in our opinion, one of the most important factors responsible for the absence of undesirable side effects from interrupting the cingulate bundles.

Problems in Assessing the Efficacy of Cingulotomy

Any protocol for assessing the results of surgical interventions for psychiatric illness must perforce be influenced by the social and economic environment in which such interventions take place. The research design used in this long-term study of cingulotorny patients was an open, prospective one. Those clinicians most familiar with the patients assessed their overall adaptation with a categorical rating between 0 and 5. This global categorization was the most clinically valid manner to assess the postoperative functioning of the patients psychiatrically, socially, and medically. These observations by clinicians who knew the patient best were most sensitive to change over time.

We cannot conclusively state that rater bias was eliminated, nor that the nonrandom treatment of patients with cingulotomy, or variations in follow-up treatment, might not have affected the postoperative assessment to a degree. The theoretical ideal of a randomized double-blind trial might have solved these problems; however, the feasibility of such a study and the loss of sensitivity in nonglobal ratings would have been potential problems. Variations in diagnostic criteria with the various DSMs, the various research

instruments used over the 20 years of this study, and the financial burden placed on the randomized unoperated patients also precluded a controlled trial.

There is another critical obstacle to an ideal scientific design when treating severely ill patients: a blinded, randomized trial of cingulotomy would be next to impossible for ethical reasons alone. Patients are only considered for operation after all other treatment modalities have failed, suffering is overwheiming, and the potential mortality considerable. Placebo or the reuse of failed treatments in a control group would not be ethical under the aforementioned conditions. This opinion is supported by the statement in the Position Paper on Psychosurgery issued by the Canadian Psychiatric Association that, "It is difficult to see how experimental procedures involving the use of 'placebo operations' could be ethically and acceptably undertaken. We therefore have to rely on a more traditional method of evaluation by objectively reviewing the responses of patients who have already received these [non-surgical] treatments" (Earp 1979, p. 359).

In 1975, the Research Committee of the Royal College of Psychiatrists proposed an experimental design for a prospective control trial to remove potential bias in assessment; however, due to societal pressures, their protocol has never been activated (Research Committee, Royal College of Psychiatrists 1977).

The Department of Psychology at the Massachusetts Institute of Technology has the only prospective study of psychosurgery wherein ratings are being done by completely independent agents, and cingulotomy, subcaudate tractotomy, and nonsurgical treatments are being compared. Provisional reports on 22 cingulotomy patients treated for severe pain have been published (Corkin and Hebben 1981). Outcome was compared from 1 to 12 years after the procedure in cingulotomy, subcaudate leukotomy, and pain unit behavioral treatment. In this comparative trial, cingulotomy was significantly more effective than either of the two other treatments.

Ballantine et al. (1972) have also reported on a series of patients in whom the first cingulate lesion was placed superior to the roof of the ventricle in its lateral radiological projection, thus sparing the inferior fibers. Only 33% of these patients improved. When those patients were reoperated upon and the lesions placed deeper in the cingulum and superior fibers of the corpus callosum, the percentage of useful improvement rose to 80%. This is not double-blind, but suggests that the improvement is not nonspecific.

In summary, vile believe that what has been obscured by lack of finesse in objective blind ratings has-bee:: compensated for by the multidimensional assessment of the quality of these patients' lives over the years. The completion of the MIT study (Corkin et al. 1979) of a consecutive group of 187 of our psychiatric patients assessed neuropsychiatrically in detail will be the necessary supplement to our global clinical assessment.

Suicide

The death by suicide of 18 patients over a mean foilow-up period of 8.6 years results in a suicide rate of 1% per year. Given the overall postoperative improvement in our population, this suicide rate stands out as a major postcingulotomy problem. Is there a relationship between suicide and the procedure? Are these suicides a reflection of the personalities of the patients, of their psychiatric illnesses, or are **they** a side effect of cingulotomy?

Suicidal ideation with major affective illness is present in 83% of our patients preoperatively. All 18 of our suicide patients had preoperative suicidal ideation, and 13 (72%) had made suicide attempts before cingulotomy. Compared to Pokomy's report

(1983) of a 1% per year suicide rate in a male population hospitalized because of affective disorders and 1.7% in those who had previously attempted suicide, and the study by Kessel and McCulloch (1966) showing suicide attempters with a successful suicide rate of 2% per year, the number of suicides in our patient population is less than expected.

Studies of suicide indicate that suicide attempters will eventually complete a suicidal act in 10% of cases. This figure increases to 15% in the case of psychotic depressives. The cingulotomy patients' suicide rate of 9% is therefore consistent with this overall mortality. The psychiatric literature indicates that the risk of death for someone with a history of a suicide attempt is between 1% and 5% per year, which is similar to the 4% per year rate in the depressed population (Kessel and McCulloch 1966).

The relief of the seventy of psychiatric illness following cingulotomy suggests that it is not the illness (usually depression) that leads to suicide. Rather, it is previous suicidal behavior, at times exacerbated by inadequately treated depression, that leads to the suicidal act.

Conclusion

Twenty-four years ago we asked two questions about stereotactic bilateral anterior cingulotomy: Is it safe, and if so, is it effective? The answer to the first is clearly affirmative. As to the second, until a method of analysis is discovered or invented that can substitute for a double-blind study, there will always be debate. Nevertheless, our rigid adherence to operating only on patients with major psychiatric illnesses previously refractory to all treatments, coupled with our length of follow-up, leads us to conclude that this procedure is a valuable adjunct in the treatment of intractable disorders of affect. Of our 198 patients, 123 (62%) experienced improvement in the quality of their lives, relief of depression, improvement in cognition, and reduction in drug abuse.

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