Essential tremor is probably the most common movement disorder recognized in the population, with a frequency of ~ 300–400 cases per 100,000 population.6 Although ET is often referred to as benign, it is anything but benign for those who suffer from it.24 It is primarily an action tremor, and may not be apparent to physicians unless they test specifically for it, whereas the tremor of Parkinson disease is mainly a rest tremor and is obvious on simple inspection of the patient. Essential tremor tends to be present mainly in the dominant hand, but bilateral tremor is common, and lower-extremity tremor and/or tremor of the head, neck, and voice may also be problematic. Patients with advanced ET are unable to write legibly or at all, cannot drink from a cup or glass without spilling, and cannot use common utensils to feed themselves. Other simple but important aspects of the activities of daily living such as buttoning clothing, brushing teeth, combing hair, applying makeup, and cooking may be difficult or impossible for those who suffer from ET. Leisure activities such as holding a book or newspaper to read, sewing, making models, using hand tools, and so on also may be difficult or impossible. In a significant number of patients with ET (~ 60%), a familial history is present, and the disorder is inherited as an autosomal dominant one, with nearly complete penetrance occurring with advanced age.2 For those with a family history, the disorder may become disabling as early as the teenage years, whereas in the nonfamilial form the tremor typically has its onset in the 4th to 5th decade of life, but may not become disabling until the 6th or 7th decade. The incidence of the disorder is approximately equal in men and women.

The underlying cause of ET is unknown, although the pathophysiological mechanism is fairly well understood.28 Recent studies suggest a tremor generator in the inferior olivary nucleus, which is then transmitted through the cerebellum to the thalamocortical motor circuits. Electrical recordings from the VIM demonstrate neurons that discharge excessively and synchronously with the tremor. For years, RFT of the VIM was the surgical procedure of choice for treatment of medically refractory ET, but more recently DBS has supplanted thalamotomy.

Abbreviations used in this paper: DBS = deep brain stimulation; ET = essential tremor; GK = Gamma Knife; GKT = GK thalamotomy; RF = radiofrequency; RFT = RF thalamotomy; VIM = nucleus ventralis intermedius.
The proponents of DBS for the surgical treatment of ET point out the nondestructive and reversible nature of this method as well as its efficacy in relieving the ET. On the other hand, DBS is an invasive procedure, and some recent studies have described a relatively high incidence of complications of DBS, including the following: intracerebral hemorrhage; tolerance to stimulation, with decreasing effectiveness over time; hardware-related complications, including lead breakage or misplacement, infection, and skin erosion; and unpleasant sensations induced by stimulation, including annoying paresthesias and dysarthria, among others.\(^1,3,4,12,19,20,44\) Patients with implanted DBS hardware may be at risk for serious and even life-threatening injuries from diathermy, MR imaging studies performed with a body coil, or electrical currents generated by surgical electrocautery equipment.\(^15,37–39,41\)

In an effort to avoid these potential complications of DBS, we have offered patients with ET the option of a VIM thalamotomy performed using radiosurgical methods with the Leksell Gamma Unit, in addition to DBS or RFT. This report describes our experience with 172 patients in whom ET was treated with 212 GKT procedures between 1994 and 2007.

**Methods**

**Patient Population**

Between February 1994 and March 2007, 172 patients underwent unilateral (130) or bilateral staged (42) VIM thalamotomy procedures with the Model U or Model C Leksell GK unit for treatment of medically refractory ET. These numbers included all GKTs performed by the senior author (R.F.Y.) during this time interval for treatment of ET. Five GKT procedures performed by other neurosurgeons during this time interval are not included in this report. Eleven patients who were lost to follow-up less than 1 year after treatment are excluded from this report. Thus, the report describes 161 patients who underwent a total of 203 either unilateral (119) or bilateral (42) thalamotomy procedures. The mean patient age was 72 ± 11 years (range 18–93 years).

**Evaluation of ET**

Patients were evaluated in a comprehensive movement disorders program that has been described in detail in previous reports.\(^35–50\) All patients had been extensively treated pharmacologically prior to being considered for surgical treatment of ET. All patients had received at a minimum both beta blockers and mycoline. In addition, at least 37 other pharmacological agents had been used in attempts to control the patients’ tremors prior to considering surgical intervention. One hundred twenty patients (74.5%) presented with absolute or relative contraindications to DBS, which included the chronic use of anticoagulants (16 patients), immune suppression (2), severe cardiovascular disease (34), age > 80 years (40), diabetes mellitus (15), and multiple other medical problems, including seizures (13). The primary assessment tool in this study was the clinical rating scale for tremor proposed by Fahn et al.\(^10\) Although we recognize multiple sources of variability in this and other measurement techniques, it is nevertheless a convenient method for tremor assessment.\(^15,30\) Assessments were made preoperatively and postoperatively at 6 and 12 months, and then annually thereafter.

**Follow-Up Protocol**

Independent tremor scoring was performed by a team of trained nurses according to a prospective follow-up protocol. Follow-up MR imaging studies were obtained at the same intervals. Prior medical management had either failed in all patients, or they could not tolerate the usual medications used to treat ET. There were 6 patients in whom prior DBS performed at other institutions had failed, even though targeting appeared appropriate and the systems appeared to function properly electrically, and 2 patients in whom prior RFT had failed. Tremor had been present for a mean of 25 ± 20 years (range 1–78 years) before GKT was performed. Deep brain stimulation and RFT in addition to GKT were discussed as surgical options with all patients. There were 76 male and 85 female patients studied for this report, of whom 96 (60%) had a family history of tremor, whereas the remainder did not have a family history. One hundred forty-six patients (91%) were right-handed, 12 (7%) were left-handed, and 3 (2%) were ambidextrous. All GK-induced lesions were made with a single isocenter by using the 4-mm secondary collimator of the GK. The target was localized using preoperative MR imaging studies obtained after placement of the Leksell Model G stereotactic frame. Detailed descriptions of our technique have been presented in previous reports.\(^35–47,49,50\) The maximum radiosurgical dose varied from 141 to 152 Gy, but since November 1999 we have used a maximum radiosurgical dose of 141 Gy for all lesions (0.87 output factor). Of the 203 procedures, 171 were performed at a maximum radiosurgical dose of 141 Gy.

Forty-two patients underwent a second, contralateral lesioning procedure between 12 and 65 months (mean 20 ± 12 months) after the first lesion to treat contralateral or axial tremor. A second lesion was made only if the first lesion had resulted in effective control of contralateral tremor, if at least 12 months had elapsed between the 2 lesions, and if an MR imaging study obtained at least 1 year after the first procedure demonstrated a lesion of the expected size (6–8 mm diameter) without significant surrounding abnormal signal changes. In no case was a repeat GK lesioning procedure performed on the same side in cases of a unilateral lesion that had failed to control tremor, and in such patients a contralateral lesion was not performed either. If a unilateral GK failed to control tremor, DBS was reconsidered as an option, as was enlargement of the lesion by RF lesioning. Three patients eventually underwent unilateral DBS placement, 1 patient underwent bilateral DBS placement, and 5 underwent a total of 6 RFT procedures after failed GKT. Of the total of 5 DBS leads eventually placed, 3 led to adequate and 2 to inadequate tremor control. Of the 6 RFT procedures performed after failure of GKT, only 3 resulted in adequate tremor control. Eighty-seven patients (54%) remain in the group receiving follow-up at a mean of 44
Gamma Knife thalamotomy for tremor

± 33 months after GKT. Thirty-one patients (19%) died at a mean of 44 ± 26 months after treatment, and 43 patients (27%) were lost to follow-up for a variety of reasons by 42 ± 30 months after treatment. The reasons patients were lost to follow-up included failure of the GK treatment and the patient’s wish not to receive follow-up, that another surgical procedure was performed, or patients requested no further follow-up even with good tremor control, or were unable to complete the necessary follow-up procedures.

Results

Clinical Rating Scale for Tremor: Overall Results

The mean preoperative tremor score for drawing was 3.3 ± 0.8, and the mean postoperative score was 1.6 ± 1.4 (51% improvement). The mean preoperative tremor score for writing was 3.1 ± 1.3, and the mean postoperative score was 1.3 ± 1.2 (58% improvement). The differences for both drawing and writing scores are statistically significant (p < 0.0001, 2-tailed t-test with Pearson correlation). See Fig. 1 for a graphic example of improvement in the drawing score. All postoperative scores were determined at the time of last follow-up, at a mean of 56 ± 31 months following the procedures. Table 1 shows the drawing and writing scores at 6 and 12 months after the procedures and at the time of the last follow-up. There were no statistically significant changes in tremor scores over time. Overall, 81% of patients showed improvements in drawing scores, with 51% having achieved a score of ≤ 1 for drawing and 68% having achieved a score of ≤ 2. For writing, 77% of patients showed improvement, with 66% having achieved a score of ≤ 1 and 84% having achieved a score of ≤ 2.

Unilateral Procedures

Strictly unilateral procedures were completed in 119 patients. For this group, the mean follow-up was 40 ± 33 months. The mean preoperative drawing score was 3.3 ± 0.8, and the mean postoperative drawing score was 1.4 ± 1.3. The mean preoperative writing score for this group was 2.7 ± 1.2, and the postoperative score was 1.2 ± 1.2. The differences for both the drawing and writing scores were statistically significant (p < 0.0001, 2-tailed t-test with Pearson correlation). Forty-two patients underwent first a unilateral and then later a contralateral (bilateral) lesion. For this group, the mean follow-up for the first lesion was 64 ± 28 months. The mean preoperative drawing score for this group was 3.5 ± 0.7, and the postoperative score was 1.4 ± 1.3. The mean preoperative writing score for this group was 3.0 ± 1.4, and the postoperative score was 1.3 ± 1.2. The differences for both the drawing and writing scores were statistically significant (p > 0.0001, 2-tailed t-test with Pearson correlation).

Bilateral Procedures

Forty-two patients underwent a second contralateral (bilateral) thalamotomy procedure at a mean of 20 ± 12 months after the first procedure. The mean follow-up period after the second procedure was 41 ± 25 months. For these patients, the mean preoperative drawing score for the side contralateral to the second procedure was 3.1 ± 1.0, and the postoperative score was 1.0 ± 0.9. The difference was statistically significant (p < 0.0001, 2-tailed t-test with Pearson correlation). Because the vast majority of bilateral procedures were performed contralateral to the nondominant hand, writing scores were not assessed for this group of patients. Thirty patients in this group were still receiving follow-up at a mean of 43 ± 26 months after their second procedure, whereas 9 patients died at a mean of 37 ± 43 months after the procedure, and 3 other patients were lost to follow-up for various reasons, all more than 4 years after the procedure.

Postprocedure Complications

Fourteen patients experienced complications at a mean of 8 months after GKT. Calculated on a per-patient basis (excluding the 4 who were lost to follow-up before any outcome could be determined), the rate of complications was 14 (8.4%) of 167. Calculated on a per-lesion basis, the complication rate would be 14 (6.9%) of 203. Of the 14 patients who experienced complications related to the procedures, 4 suffered only limited sensory loss contralateral to the side of the procedure, and in 2 of these patients the sensory loss completely resolved. One of the patients who suffered transient sensory loss following the GK procedure went on to have a contralateral thalamic DBS implant at another institution and suffered speech impairment after the DBS procedure.

TABLE 1: Writing and drawing scores in patients with ET before and after GKT†

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Preop</th>
<th>6 Mos</th>
<th>12 Mos</th>
<th>Last FU</th>
<th>% Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>writing</td>
<td>3.1 ± 1.3</td>
<td>1.26 ± 1.1</td>
<td>1.04 ± 0.9</td>
<td>1.3 ± 1.2</td>
<td>58</td>
</tr>
<tr>
<td>drawing</td>
<td>3.3 ± 0.8</td>
<td>1.72 ± 1.0</td>
<td>1.51 ± 1.2</td>
<td>1.6 ± 1.4</td>
<td>51</td>
</tr>
</tbody>
</table>

* FU = follow-up.
† Calculated according to the system of Fahn et al. The differences between the pre- and postoperative scores are statistically significant, but there are no statistically significant differences between the scores at 6 and 12 months and at the time of the last follow-up. See text for details.
lead subsequently fractured and a reimplantation was accomplished, but tremor control contralateral to the DBS was only fair (tremor score of 2), whereas contralateral to the GKT the patient was tremor free. No patient with only sensory loss suffered any functional consequences of the loss, and only 1 patient found the sensory loss at all bothersome.

Ten patients suffered varying degrees of motor impairments, and 5 of these also suffered varying degrees of speech disturbances after GKT. Of these, 1 patient experienced temporary difficulty with control of the foot contralateral to the GK lesion, which totally resolved. Of the remaining 9 patients, 3 experienced mild hemiparesis (mainly difficulty dragging the contralateral leg while walking), and 1 experienced moderate hemiparesis and mild dysarthria, but they eventually made full recoveries. Six patients experienced more significant contralateral weakness and speech disturbances, but all patients showed progressive improvement over periods of 12–18 months after the treatments.

Thus, overall, considered on a per-lesion basis, there were 8 permanent complications (3.9%), of which 2 were strictly sensory in nature and of no functional consequence. Interestingly, not a single patient who underwent a contralateral (bilateral) procedure developed any complications related to the procedures. There was a clear-cut correlation between lesion volume and complications. The mean lesion volume for the 157 procedures in which no complications were identified was $224 \pm 742$ mm$^3$, and for the 14 procedures following which complications were identified, the mean lesion volume was $871 \pm 742$ mm$^3$ ($p < 0.001$, t-test with 2 samples assuming unequal variances).

**Discussion**

**Surgical Options for Patients With ET**

The 3 options currently in use for the surgical treatment of ET include the following: 1) RFT; 2) DBS; and 3) radiosurgical thalamotomy with the GK (referred to here as GKT). Although RFT is rarely used today, a recent report suggests that the procedure may still be useful and even preferable to DBS in certain selected patients. Its advantages include immediacy of the results, ability to corroborate the target electrophysiologically, and ability to increase the size of the lesion slowly and gradually while the patient’s responses are observed. In spite of these advantages, the rate of undesired neurological sequelae is fairly high even for unilateral procedures, and bilateral procedures are rarely performed due to the unacceptably high rate of complications. Recurrent tremor is fairly frequent, and repeat procedures may be necessary to accomplish the desired reduction in tremor.

The DBS procedure is probably the one currently performed most frequently for surgical treatment of ET. The rate of successful tremor relief is high; however, the rate of neurological complications, particularly with bilateral procedures, is significant, and late tremor recurrences, in spite of optimal programming of the stimulators, continue to occur. In addition, hardware complications are relatively frequent, often requiring surgical interventions. Additionally, some patients with ET may not be candidates for DBS due to advanced age, long-term use of anticoagulants, or other serious medical conditions. The GKT procedure offers a surgical treatment for ET that is roughly similar in efficacy to DBS in relieving tremor, but it has its own set of complications, mainly due to excessive reactions to radiation, which result in significant and sometimes permanent new neurological impairments.

**Outcomes After GKT**

The GKT procedure is an effective treatment for medically refractory ET. We assessed our outcomes using only the writing and drawing subscores of the clinical rating scale for tremor proposed by Fahn et al., because these parameters are easy to obtain over long-term follow-up and are, we believe, an excellent indication of the efficacy of surgical treatments for ET. Our results showed an average 58% improvement in writing scores and a 51% improvement in drawing scores. Overall, 81% of patients showed improvements in drawing and 77% in writing scores.

The initial and long-term rates of tremor control compare favorably to those achieved with DBS. Kondziolka et al. recently described their experience with GKT for the treatment of ET in a group of 31 patients. Their results showed statistically significant improvements in tremor scores and handwriting scores according to a scoring system identical to that which we have used. Ninety-two percent of 26 evaluable patients in their study showed improvements in either action tremor, writing scores, or both. These results are comparable to those that we and others have described in earlier communications concerning our experience with GKT for treatment of ET in smaller numbers of patients with shorter follow-up periods than in the present report. Like Kondziolka et al., we did not score head, neck, or voice tremor, but like those authors we also noted frequent and significant improvements in midline tremor. We also made the qualitative observation that midline tremor was improved more significantly following bilateral than unilateral procedures.

**Complications of Radiosurgery**

Certainly GKT is attended by infrequent but sometimes serious complications caused by idiosyncratic and unpredictable excessive radiation reactions. Okun et al. described 8 patients who had sustained serious complications related to radiosurgical lesioning procedures performed with the GK unit for the treatment of movement disorders. However, the total number of patients who had undergone lesioning procedures at the institution in question was unknown, and therefore, it was impossible to calculate the actual incidence of such complications. In our extensive and well-documented experience, complications of GKT performed using the methods that we have described are unusual. In the Kondziolka et al. report, 2 patients suffered delayed adverse effects of the GKT procedures due to lesions of an unexpectedly large size, a risk of 7.7%, which is very similar to the complication
rate of 6.9% that we describe in the present report. As with the 2 patients in the Kondziolka et al. report, half of the patients in the present report who sustained complications related to the procedures eventually made a good recovery, so that permanent neurological deficits were identified in only 3.9%.

Rare idiosyncratic unintended results have been described in 2 patients after GKT, including pseudobulbar laughter in one and complex involuntary movements in another.\textsuperscript{28,40} We have never seen such results in our large series of patients followed over many years. Unfortunately, when complications of GKT do occur there is little effective treatment. Corticosteroids may be somewhat effective in temporarily reducing symptoms, but there is little if any documented effect of these agents on the long-term outcome. The excessive radiation response that produces such complications typically has its onset 6–12 months after a procedure, proceeds to reach a peak in 1–3 months, and then subsides over an additional 12–18 months. Distressing as they are, such complications do not often result in permanent neurological disability (although rarely they may), and the process can nearly always be managed on an outpatient basis.

Failure to achieve tremor control may also be considered a complication of GKT. Ohye and colleagues\textsuperscript{26,27} assessed the thalamic lesions produced by GKT and suggested that failure of the procedure was related to lesions that do not completely destroy the thalamic “tremor cells.” Failure of GKT is virtually always associated with a lesion that is smaller than expected, rather than one that is not ideally located anatomically. We found a statistically significant difference between the volumes of lesions that resulted in tremor control when compared with those that did not. This finding is further confirmation of the variability in lesion volumes that results from radiosurgical lesioning, and in our opinion is the major limitation of GKT for treatment of ET.

Comparison Between GKT and DBS

It is important to consider, in making comparisons between GKT and DBS, that the two patient populations are not identical. Patients who receive DBS tend to be younger and healthier overall than our patients. For instance, the mean age in our patient population was 72 years, with a range from 18 to 93 years, whereas in a large long-term outcomes study of DBS for ET,\textsuperscript{5,30,22,31,33,36,42} the mean age ranged from 60 to 70 years, averaging ~ 65 years across the 7 studies, or a full 7 years younger than our patient population. Very few patients older than 80 years of age are included in the DBS studies, whereas 40 (23.3%) of our 172 patients were older than 80. Although all of the reports that we will use to compare our results to those of DBS also used Fahn et al.’s\textsuperscript{10} clinical rating scale for tremor, some authors chose to use individual writing and drawing scores, exactly as we have done, whereas others chose to use various different aggregate scores. In none of the cited reports on DBS for ET was the total composite clinical rating scale for tremor score reported. To simplify the comparison, we calculated the percent improvement in clinical rating scale for tremor scores as reported by the various authors,\textsuperscript{5,20,22,31,33,36,42} which ranged from a low of 46% to a high of 75%, and averaged ~ 60%. This compares favorably to our improvement rates of 58% for writing and 51% for drawing.

In addition, some authors have explored stimulation targets for ET other than the VIM thalamus, such as the subthalamic region\textsuperscript{13} in patients whose disease was refractory to thalamic stimulation, and one such author\textsuperscript{23} indicated that some patients did not respond to stimulation of either target, and concluded that such patients may “… constitute a subgroup less responsive to DBS.” Also, whereas we accomplished bilateral GKT in 42 patients without a single complication, bilateral DBS is accompanied by a relatively high complication rate, and a recent report\textsuperscript{31} has recommended against bilateral DBS for treatment of tremor. Some recent reports describe dysarthria and disequilibrium in 30–50% of patients who undergo bilateral thalamic DBS.\textsuperscript{13,23,34}

We found neurological complications of GKT in 8.7% of patients and 6.9% of procedures. Of these, permanent neurological complications were experienced in patients undergoing 3.9% of GKT procedures. Beric et al.\textsuperscript{5} reported permanent neurological sequelae in 6% of a group of 86 patients who underwent DBS procedures; however, 26 (30%) of 86 suffered some adverse event as a result of the DBS procedures. Grill\textsuperscript{11} indicated that permanent neurological sequelae resulted in 4–6% of patients who underwent DBS, and that the overall complication rate can exceed 25%. Ellis et al.\textsuperscript{26} recently described their experience with reoperation for suboptimal outcomes after DBS surgery for movement disorders. These authors discussed the multiple factors that may result in such suboptimal outcomes, such as shift of the stereotactic frame during the procedure, poor technique, lack of expertise, incorrect interpretation of microelectrode recordings, lead deflection during implantation due to the use of a short implant cannula, or differences in tissue density. They also discussed so-called lead dislocation, which can occur during attempts to secure the DBS lead in place after implantation. Although their report indicated that repositioning could often lead to improvements in outcomes, they cautioned that reimplantation “should not be considered risk free” and that even with what appeared to be adequate repositioning of leads, “not all patients operated on in our series had improvements, and a few experienced worsening on motor scales.” Ellis et al. also suggested that due to variations in the evaluation of outcomes at different DBS centers “… it is conceivable that a subset of patients may be experiencing issues that are not correctable by reoperating (revising/repositioning) the lead.”

In the literature on DBS for ET, failure of the procedure is rarely discussed,\textsuperscript{14} nor is it addressed as a complication. In this regard, Papavassiliou et al.\textsuperscript{35} indicated a true physiological tolerance of 9% to DBS in patients in whom they judged the DBS leads to be optimally placed. Koller et al.\textsuperscript{20} indicated that of 49 patients who underwent thalamic DBS implants for treatment of ET, 3 did not undergo a permanent implant and the devices were explanted in 7 patients < 24 months after implantation because of unsatisfactory tremor control. Thus, there was a failure rate of 20%. In a recent report, Pilitsis et al.\textsuperscript{33} described a failure rate of 18% (4 of 22) at a mean of 40 months after thalamic DBS for treatment of ET.

Hamani and Lozano\textsuperscript{22} reviewed published reports on
922 patients who underwent DBS procedures for treatment of movement disorders and indicated that infections occurred in 6.1%, migration or misplacement of the electrodes in 5.1%, lead fractures in 5%, and skin erosion in 1.3%. In total the complication rate was 17.5%. In addition to these problems with DBS for treatment of ET, and others that we have referred to previously in this report, one must consider the time and expense necessary for programming the DBS systems and the cost of the regularly required battery replacements. A recent report indicates that the mean nursing time spent assessing patients with DBS and programming their stimulators ranged from 18.0 to 36.2 hours per patient.19 Because the DBS systems remain in place, the need to replace fractured electrodes adds to the expense of the procedure. In our view, if one can achieve reasonably comparable tremor control in ET by using GKT, without the need for hardware implantation, then that would appear to be a preferable treatment approach. Putzke et al.35 observed that bilateral DBS of the VIM was associated with a more significant improvement in midline tremor than unilateral DBS. Interestingly, these authors described a 27% incidence of dysarthria with bilateral DBS, and a 20% rate of electrode repositioning or replacement.

In summary, it appears that the outcomes in terms of tremor control and neurological complications are quite similar when comparing GKT to DBS. The primary difference is the lack of hardware-related problems with GKT.

Conclusions

Gamma Knife thalamotomy is an effective procedure for the control of ET. The degree of improvement is comparable to that achieved with DBS. The permanent complication rate of 3.9% also compares favorably with the reported complication rate of DBS. The GKT procedure is particularly useful in patients who are not ideal candidates for DBS, such as those older than 80 years of age, or those who have used anticoagulants over a long period or have other associated conditions that may contraindicate DBS. The opportunity to achieve tremor control without the need for implanted hardware and the associated need for programming and battery changes is an attractive feature of GKT. Although GKT is particularly suited to patients who are not ideal candidates for DBS, we believe that it should be discussed as an option with all patients who are candidates for surgical intervention for the treatment of ET.

Disclosure

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Gamma Knife thalamotomy for tremor


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