MedStar Health

September 23, 2005

VIA U.S. MAIL AND VIA FACSIMILE
(610) 337-5241 and (610) 337-5269

Mr. Samuel J. Collins
Regional Administrator, Region I
United States Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406

Ms. Pamela J. Henderson
Chief, Medical Branch, Region I
United States Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406

Re: Follow-up to Reporting of Event Occurrence

Dear Mr. Collins and Ms. Henderson:

Enclosed please find materials which are intended to comply with the requirements of 10 C.F.R. § 35.3045(d). As you may be aware, the Washington Hospital Center ("WHC" or the "licensee") recently complied with the requirements of 10 C.F.R. § 35.3045(c) and reported an event which occurred on April 9, 2003 upon instruction of Ms. Penny Lanzisera of your office after it was recently informed that technical advisors from the Nuclear Regulatory Commission ("NRC") Headquarters have definitively concluded the occurrence constituted a reportable medical event.

At the time of the occurrence, WHC concluded that the incident was not a reportable medical event; however, the patient and the referring physician were immediately informed of the incident, as well as the Radiation Oncologist, Dr. Robert White's conclusion, that there was no clinical significance to the patient resulting from the incident. The licensee maintains this incident was not a reportable medical event and the patient is already aware of the circumstances, hence, WHC has not re-contacted the patient directly to inform them of this recent report to the NRC. However, the referring physician is aware of the ongoing discussions with the NRC.

WHC has been in regular contact with your office about this occurrence since March 27, 2005, when the NRC raised potential concerns about the incident. WHC has thoroughly reviewed and investigated the matter, and has responded to each of multiple different requests from the NRC for additional information about the circumstances. Despite these multiple cooperative discussions and reporting submissions, the NRC felt compelled to request technical assistance from NRC Headquarters and ultimately engaged the assistance of an outside consulting Radiation Oncologist to review the case and to interview the licensee.

Although WHC strongly disagrees with the NRC's assessment of this matter, WHC would like to take this opportunity to summarize the facts relating to this occurrence, the rationale for its determination of why it was not a reportable medical event, clarify its prior reports, correct an error that was previously reported, and provide the legal support for its position.

Factual Background

On April 9, 2003 a patient underwent an 11-stop Gamma Knife treatment for a left acoustic neuroma. Due to the location of the tumor, the Radiation Oncologist and Neurosurgeon exercising their professional judgment, determined that the right anterior fixation pin of the stereotactic apparatus which holds the patient skull in place needed to be removed to avoid collisions with the pin during the Gamma Knife treatments. This resulted in only three (3) fixation points holding the stereotactic frame, instead of the maximum four (4). However, without removal of this fixation pin, planned treatment positions could not be attainable and the patient would have to forego treatment. The physicians have been trained in this 3-pin technique and the 3-pin technique has been scientifically validated.[1] Moreover, the physician's involved have a number of years of experience in positioning and setting the stereotactic frame on patients and positioning it in the Gamma Knife apparatus.

This particular patient was a very large person who had a very large head which required the head to be positioned medially in the frame. The neurosurgeon followed the manufacturer's guidelines for tightening the fixation points, manually attempted to move the frame upon the patient's head, and confirmed via Magnetic Resonance Imaging ("MRI") that the frame was stable on the patient's head and had not shifted. Upon removal of the pin, both the Neurosurgeon and Radiation Oncologist confirmed that the fixation points were stable by checking the positioning of the frame through insertion into the Gamma Knife apparatus. No indication of movement or inadequate tightening was identified.

The patient successfully underwent the first 10 stops of treatment without incident. Unfortunately, at a point during the second half of the 11th and final treatment stop (lasting less than 1 minute), the patient coughed or sneezed resulting in dislodgment of the sole anterior pin resulting in a 6mm shift on the skull level. When the muffled sound from the patient was observed, the Radiation Oncologist immediately queried the patient to determine if there had been any problems. The patient relayed he was fine and made no indication of frame movement. Having no reason to believe that the apparatus had shifted, the session proceeded to termination. At the end of the session, it was observed that frame appeared to have slightly shifted at the location of the left anterior pin.

The Radiation Oncologist in conjunction with the Chief Medical Physicist, after considering the degree of pin shift, dose delivered, duration of delivery, and likely location of the delivery site determined that there was no unintended permanent functional damage to any organ or system a result of the incident. After further review by the Radiation Safety Officer and other institutional officials, it was reasonably determined that patient intervention resulting from the cough or

[1] See enclosed, MacKenzie, James T., et. al, *Validity of Stereotactic Frame Localization During Radiosurgery After One Fixation Pin Removal*, J. NEUROSURG (SUPPL 5) 97:539-541, (2002).

sneeze and the force exerted upon the frame due to the patient's large size and weight, was the exclusive root cause of the event. The licensee could have neither planned for, nor prevented the occurrence absent forgoing treatment on this patient entirely. Since this occurrence, WHC has not performed any Gamma Knife treatments utilizing a 3-pin technique.

On March 31, 2005, following an expression of concerns about the incident by Ms. Lanzisera, the WHC Radiation Safety Officer provided the NRC with supplemental information to address the NRC's question about the Gamma Knife incident. Included in those materials was a report created by Rosanna Chan, Ph.D., Chief Medical Physicist which described the event occurrence.

On or about May 18, 2005 after conducting an initial review of the matter, and despite NRC's later contention that items submitted by Dr. Chan were not readable, WHC was advised of NRC's conclusion that this incident should have been reported as a medical event under the NRC's required reporting provisions. We presumed, that without significant factual analysis, the NRC somehow concluded the event did not result from patient intervention. However, NRC never formally communicated the basis for their conclusion.

As a result, on or about June 15, 2005, WHC and the NRC had a conference call and it was agreed that WHC would provide supplemental information to the NRC. Among the materials requested were further information about the dose and site delivery location, but no specific further inquiry about the head frame set-up or facts surrounding the frame setting. The NRC was also provided with copies of or reference to the article identified above which scientifically validates the 3-pin technique.

In early July, WHC was again contacted by the NRC with specific additional requests for information and "readable" images relating to the estimated delivery site and dosage. No specific inquiry was made about the frame placement or related facts. Due to vacation schedules, conference schedules and an office renovation, WHC was not able to respond until August 4, 2005. In that response, Dr. Rosanna Chan provided provide restatements of her initial report in response to the requested information along with digital color images representing WHC review of the matter. We were subsequently advised that the NRC could not interpret the images and that they had engaged a Radiation Oncologist to review the materials and interview the licensee who was scheduled for September 12, 2005.

Patient Intervention Determination

On September 8, 2005, I was informed by Ms. Lanzisera in a telephone conversation, that the NRC technical advisers issued a report, without consulting or waiting for their own Radiation Oncologist's review of the factual circumstances, which concluded (paraphrasing) that after reviewing the submitted materials, discussions with the device manufacturer, and discussions with other unnamed sources, three factors potentially contributed to this incident: 1) the 3-pin technique along with inadequate tightening of the single anterior pin; 2) the rotational forces exerted by the equipment during movement through the 11 stages of treatment; and 3) the patient's coughing/sneezing. As a result, the NRC apparently concluded that the event was ***not solely due to patient intervention*** and hence would be reportable if the dose delivered off-site met the regulatory thresholds.

We believe this conclusion was made without a factual basis and we believe is a flawed interpretation of the NRC's regulatory requirements. Specifically, there is no indication at all that the sole anterior pin was inadequately tightened. To the contrary, evidence from the witnesses present, their employment of their medical judgments and experience, as well as the documented medical records shows no indication of inadequate tightening. The NRC's conclusion that the sole pin was inadequately tightened on the basis of a resultant positional shift presumes that no pin can ever shift once the head is properly tightened in the frame. In fact, physicians use their medical judgment to determine adequate tightness of each of the pins and do not tighten the pins to a degree that would prevent all movements under extreme forces. To do so would result in potential fracture of the patient's skull or damage to the brain. Nor is such tightening recommended by the device manufacturer.

In addition, there is no reason to believe that any rotational forces resulting from device movements through the treatment stages contributed in any way to this dislodgement. The rotational forces exerted by the Gamma Knife device are minimal and such a conclusion is purely speculative and not based on any fact.

Finally, utilization of the 3-pin technique is not prohibited, nor is it an action which negates patient intervention as the cause of an incident. As discussed above, even when utilizing the traditional 4-pin technique, pins cannot be fixed in a completely immovable manner and they can become dislodged due to patient intervention.

As you are aware, NRC regulations require reporting of certain qualifying medical events; "except for an event *that results from* patient intervention"[2] The regulation does not impose an exclusivity standard or require reporting of any event "except for an event that results *exclusively from patient intervention.*" Had the NRC desired such a standard it should have made it a regulatory requirement. Therefore, whether or not inadequate tightening, the 3-pin technique or rotational forces may have contributed to this incident, such factors would not eliminate the ability for licensees to reasonably conclude that patient intervention was the root cause, and hence, not reportable.

Similarly, application of such an artificial standard would appear to create agency policy in substitution of regulatory language that was explicitly removed by the NRC from its proposed regulations. I refer you to the commentary discussion of the NRC's revised regulations found at Federal Register/Vol. 67, No. 79, April 24, 2002 (FR 20331).

> Issue 6: Does the Proposed Rule Adequately Address Patient Intervention?
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> Comments. The NRC received a range of responses to the Commission's question on whether the proposed rule adequately addressed patient intervention (i.e. ***actions by the patient such as dislodging (emphasis added)*** or removing treatment devices or prematurely terminating treatment)... ***A number of commentators said that the phrase in the proposed rule "that could have been prevented by the licensee" was ambiguous and subjective (emphasis added)***, and should be deleted because it would result in varying interpretations between NRC and licensees. In addition, ***decisions on what are considered "reasonable medical practices" for patient control***

[2] 10 CFR § 35.3045(a).

infringe on the practice of medicine and should be left to the physician's professional judgment (emphasis added). Therefore, this requirement is in violation of Statement 2 of the proposed revision of the Medical Policy Statement: ***NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public (emphasis added).***[3]

Response. As part of the medical use rulemaking, the Commission ***is codifying a common-sense approach to the reporting requirements for medical events that excludes incidents involving patient intervention. (emphasis added)*** In the proposed rule, the phrase "that could not have been reasonably prevented by the licensee" was added to § 35.304(a) in an attempt to avoid further expenditure of resources by licensees and NRC in trying to determine what constitutes patient intervention, which is not specifically addressed in the current rule. The issue has involved whether or not a licensee did everything it should to prevent patient intervention during treatment that resulted in a medical event. Following our evaluation of the comments on patient intervention, ***the NRC deleted the proposed phrase from § 35.3045(a) because it did not seem to clarify when an event caused by patient intervention must be reported to NRC as a medical event (emphasis added).***

In the final § 35.3045(b), we addressed the issue of when an event caused by patient intervention must be reported to NRC as a medical event. In addition, we added a definition of patient intervention to § 35.2. ***As defined, patient intervention means "actions by the patient or human research subject, whether intentional or unintentional such as dislodging or removing treatment devices or prematurely terminating the administration." (emphasis added).*** We believe licensees ***<u>should only be required to report serious</u> medical events due to patient intervention (emphasis added).***

Paragraph (b) of this section in the final rule requires licensees to report any event resulting from intervention of a patient or human research subject in which the administration of by-product materials or radiation from by-product material results ***or will result in unintended permanent functional damage to an organ or a physiological system as determined by a physician (emphasis added).*** As a result of the significantly higher threshold, ***the NRC <u>will only</u> receive reports involving patient intervention for events with serious consequences (emphasis added),*** (e.g. unintentional permanent functional damage).

This reporting requirement ***should result in decreased regulatory burden on licensees (emphasis added)*** because in most situations where patients intervene in their treatment, either voluntarily or involuntarily, there is no permanent functional damage. ***Therefore, the revised reporting requirement should significantly reduce the resources expended by the NRC and licensees in debating what are considered reasonable medical practices for patient control because the NRC will no longer require most of the reports it currently receives involving patient intervention. In addition, it should avoid intrusion into medical judgments by the NRC because the decision on whether the administration resulted in permanent functional damage to an organ or a physiological system is to be determined by a physician. (emphasis added)***

In relevant part, the NRC specifically removed from its proposed regulations the reportability of patient intervention "that could have been prevented by the licensee" agreeing that the standard was ambiguous and "would result in varying interpretations between NRC and licensees." Instead, the NRC specifically chose a standard that acknowledged the "decisions on what are

[3] This position was adopted as the NRC's Statement of General Policy at 65 FR 47645 (Aug. 3, 2000).

considered 'reasonable medical practices' for patient control infringe on the practice of medicine and should be left to the physician's professional judgment."[4]

WHC is concerned about the basis for the NRC's conclusions and about the development of a reportability standard not contemplated by the NRC's regulatory authorities or guidance which effectively eviscerates the regulatory framework established by the NRC. Unfortunately, and ironically, the NRC's approach to this occurrence appears to have resulted in precisely the conflict and waste of resources this regulatory revision was intended to avert.

As a result of the foregoing, WHC believes it reasonably concluded that the patient's intervention was the root cause of the event and it has no reason to believe that any other factors contributed to the event nor does it believe it has a reportability obligation for this occurrence under existing NRC regulations and guidance.

Dosage Level Criteria

Notwithstanding the foregoing, in addition to believing this matter was not reportable, WHC strongly believes that the dose delivered off site does not even qualify as a medical event under NRC regulations.

In my phone conversation with Ms. Lanzisera of September 9, 2005 she also relayed the NRC technical advisers conclusion which accepted as fact that the patient received 760 rem approximately 6mm off site when they were expected to receive 260 rem in violation of 10 C.F.R. § 35.3045(a)(3). As she and I discussed, I was somewhat puzzled by those figures and couldn't understand how they were derived. I pointed out to Ms. Lanzisera that we had reached a different conclusion on the doses, yet she was unable to offer an explanation of how the figures were derived.

Regrettably, upon further review of the materials submitted we've discovered one issue that should be clarified from our prior reports and a second issue that we believe was reported incorrectly, both of which would have an impact on the dose level conclusions. Unfortunately, we were not able to discover these omissions until we examined the reports further because we did not adequately understand what Dr. Chan was conveying.

First you'll notice that the reports generated by Dr. Chan described a "worst-case scenario" and are theoretical in nature not factual because they do not accurately represent the likely site location for the following reasons.

The reports suggest a site location that was 6mm off site. In fact, the 6mm shift represents the pin shift at the scalp level. Because of the position of patient in the device, the position of the tumor, and the fact that the posterior pins did not shift, it is improbable to conclude that the unintended dose site was also a full 6mm off. Unfortunately, however, there is no adequate way of determining the precise location off site, hence the 6mm figure was provided as a theoretical worst case scenario.

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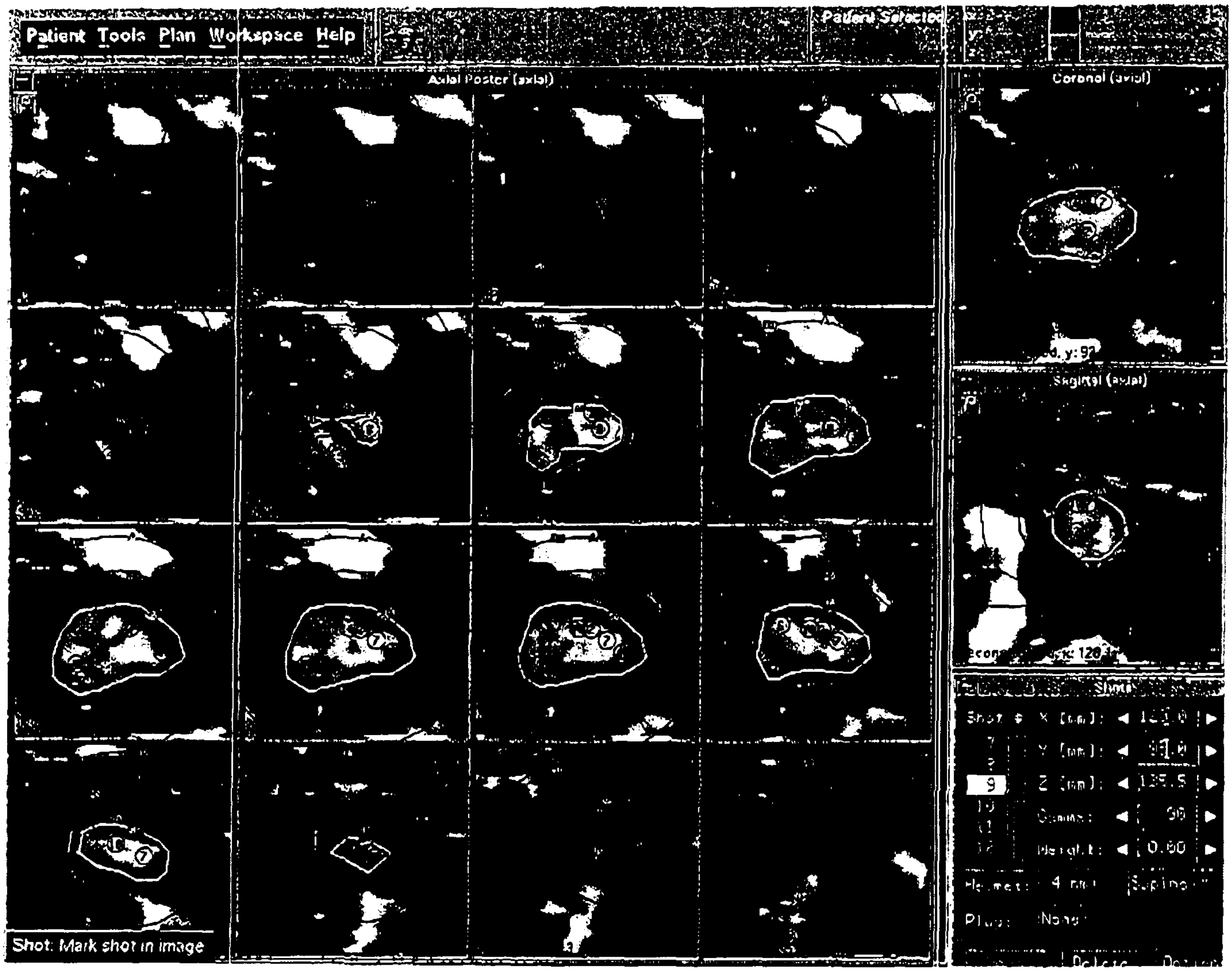
[4] The NRC further concluded that only serious medical events resulting from patient intervention and resulting in unintended permanent functional damage shall be reported to the NRC.

Second, Dr. Chan's report of August 4, 2005 – Figure 6, suggest that the unintended dose location was between the 10% (2.6 Gy) and 20% (5.2 Gy) isodose lines. After further review, it appears we referred the NRC to the wrong image and that the text does not accurately reflect the unintended site location. As you can see from the Figure #6 from Dr. Chan's report pasted below, the correct image representing the off site location would be at Z coordinate 135.5 which is the image in row 2, column 2. As you can see from that image, the dose location off site at target would be at approximately the 30% isodose bar range.



Again, however, these images reflect the estimations based on the 6mm off tumor calculations which have their own faults as described above. It's likely that the shot at target was even closer to the tumor. Nonetheless, by our calculations the dose expected at the 30% isodose line would be 780 rem. The unintended dose if delivered in its entirety off site would be 518 rem. However, please recall that the patient intervention occurred at least ½ way through the final sequence. As such, we calculated the unintended dose at this level to be no more than 259 rem additional to the unintended site. By these calculations, we don't believe the medical event

criteria of 10 C.F.R. § 35.3045(a)(3) is established. Furthermore, we would point out again that the unintended site location at target was the auditory canal which again resulted in no patient harm, nor is that a location that fits the criteria of the above regulation.

As a result of the foregoing, WHC believes it reasonably concluded that the patient's intervention was the root cause of this event and it has no reason to believe that any other factors contributed to the event. We've further concluded that even if patient intervention was not a factor, the incident did not rise to the regulatory threshold for a medical event.

The Washington Hospital Center appreciates the role of the NRC in regulating licensee activities and in attempting to assure patient safety, and we've been as forthcoming as possible with the NRC, its advisors, its consultants about this occurrence. We hope that the NRC will be able to raise any continuing concerns that they may have about this incident with WHC and that this matter can be resolved through an appropriate dialogue with its representatives.

We hope that you will share this report with the NRC's technical advisors and medical consultants, particularly the discovery of the errata previously reported to the NRC and that the NRC will reconsider its prior conclusions.

Thank you for your review and attention to this matter. We look forward to discussing the enclosed materials and addressing any other issues the NRC may wish to discuss. I can be reached at (202) 444-3553.

Sincerely,

Alexander D. Eremia, J.D., LL.M.
Associate General Counsel

Enclosures

Cc: Shashadhar M. Mohapatra, Radiation Safety Officer
Robert L. White, M.D., Radiation Oncologist
Jeffrey Jacobson, M.D., Neurosurgeon
Rosanna Chan, Ph.D., Chief Medical Physicist
Jeffrey Matton, Vice President, Professional Services

J Neurosurg (Suppl 5) 97:539–541, 2002

Validity of stereotactic frame localization during radiosurgery after one fixation pin removal

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Object. This study was designed to examine the effect on target localization of removing one fixation pin or post.

Methods. A stereotactic frame was applied to a head phantom by using four fixation pins. Contiguous axial computerized tomography (CT) slices (1 mm thick) were obtained through the head phantom. Using clinical treatment planning software, a marker was identified and its coordinates were determined. The imaging procedure and point localization were repeated independently seven times in the control configuration after four-pin fixation, to study reproducibility.

Standard deviations in marker coordinates were 0.013, 0.046, and 0.039 mm along the x, y, and z axes, respectively, indicating excellent reproducibility. Each of the four pins was then removed separately, leaving three pins providing fixation to the skull. Imaging was repeated for each three-pin configuration. To simulate the forces at each pin-skull interface, a lever arm was connected to the head phantom allowing application of variable torque to the system. The CT scans were obtained for each torque strength and pin removal combination. Marker coordinates were compared with the control.

Conclusions. In most cases, it was found that accurate target positioning could be achieved after removal of a single pin and/or post. When high torque was used, however, removal of a pin resulted in up to a 1.2-mm error. The findings may be significant for clinical practice, depending on the condition being treated.

KEY WORDS • stereotaxy • localization • gamma knife • collision

THE Leksell Gamma Knife (Elekta, Stockholm, Sweden) delivers a highly focused radiation dose that is used to treat both benign and malignant intracranial lesions. The treatment procedure involves the localization of a target lesion by using CT or magnetic resonance imaging and then delivering radiation "shots" to those sites. Each radiation shot involves the combination of 201 highly focused beams of radiation emitted from ^{60}Co sources that converge on a centrally positioned target. The exact (x, y, and z) coordinates of the target for each treatment are determined using a fiducial marker reference system positioned about the patient's head during imaging. Treatment planning is performed using a commercially available software package (GammaPlan; Elekta). Varying the time of exposure and using different sized collimator helmets can alter the shape and intensity of each radiation shot delivered during a GKS procedure. Typically, a combination of several shots is required to cover an irregularly shaped target adequately.

Abbreviations used in this paper: CT = computerized tomography; GKS = gamma knife radiosurgery.

Treatment with GKS is performed with a stereotactic frame invasively secured to the patient's skull. A fiducial marker system attached to the frame during imaging allows a transformation of patient anatomy to the stereotactic system using the GammaPlan software. Standard stereotactic frame application involves the use of four fixation pins to attach the frame securely to the patient's head. During treatment, there are times when a shot cannot be delivered because of a collision between either the patient's head or frame and a collimator helmet. Occasionally, it is possible to remove the pin or post responsible for the collision and continue treatment. The aim of this work is to identify the accuracy of treatment delivered with three-pin fixation when all imaging and planning have been performed based on four-pin fixation.

Materials and Methods

A stereotactic frame was applied to an anthropomorphic head phantom (Rando; The Phantom Laboratory, Salem, NY) by using four fixation pins in the standard clinical protocol. A clinical fiducial marking system was attached to the frame. Contiguous axial CT

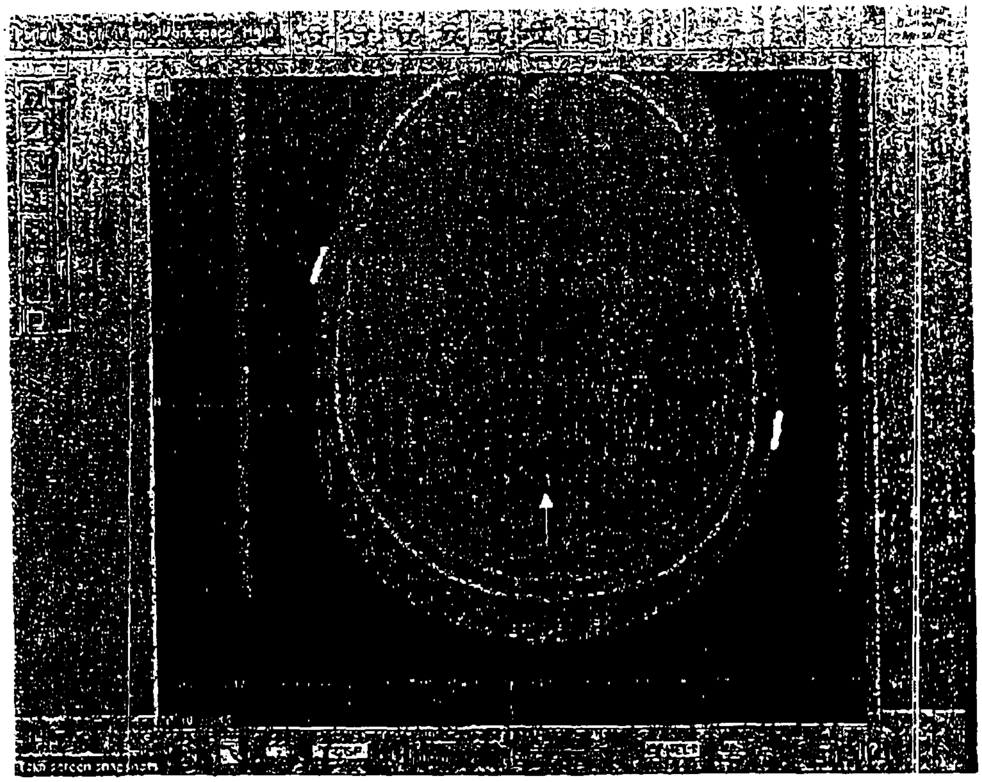

FIG. 1. Axial CT slice through the anthropomorphic head phantom. The *arrow* points to the marker that was localized under different pin removal and applied torque conditions.

slices (1 mm thick) were obtained from the base of the frame to the top of the skull. All images were then transmitted over a local area network to the GammaPlan system. On transformation to the stereotactic coordinate system, a small 1-mm marker was identified within the image set (Fig. 1) and its spatial coordinates (x, y, and z) were recorded. The position of the marker within the phantom was slightly posterior in the y axis and in the midline in the x axis. Reproducibility was assessed by independently repeating the imaging procedure and point localization for the four-pin fixation seven times in the control configuration. Next, a single pin was removed and the experimental procedure was repeated. A 15-cm-long lever arm was constructed and attached to the inferior part of the phantom (Fig. 2) to simulate forces at the pin-skull interfaces resulting from awkward patient positioning within the collimator helmet during treatment. Different forces were then applied at the end of the lever arm to provide different torques that produced varying forces at the pin-phantom skull interfaces. Varying torque strengths were used in different experiments based on estimates of low, normal, and high forces that might influence the stereotactic frame positioning relative to the patient's skull during a clinical treatment. Separate CT scans were acquired for each torque strength and pin removal combination. The location of the marker was identified in each image set and compared with the control values.

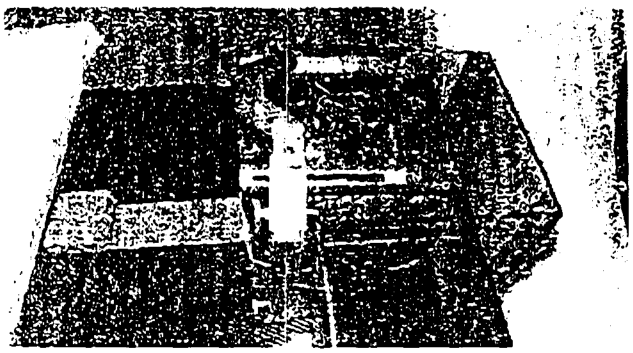

FIG. 2. The anthropomorphic head phantom with stereotactic head frame and fiducial apparatus applied. A lever arm with applied modest weight is also shown.

Results

Standard deviations in marker coordinates localized on CT scans obtained with all four fixation pins in place and no torque applied were 0.013, 0.046, and 0.039 mm along the x, y, and z axes, respectively, indicating excellent localization reproducibility. Furthermore, in all seven control experiments, both intra- and interobserver reproducibility were excellent. Table 1 shows shifts in marker coordinates after application of varying torques with three-point fixation. Removal of the right anterior pin showed little reference coordinate deviation from the control values. With approximately 6.5, 11.3, and 27.8 Nm of torque (minimal, intermediate, and maximal) applied in three different experiments, the coordinates deviated from the control by 0.1, 0.1, and 0.0 mm, respectively, in the x plane; 0.34, 0.14, and 0.14 mm, respectively, in the y plane; and 0.07, 0.03, and 0.07 mm, respectively, in the z plane. Similarly, removal of the left anterior pin when applying an even higher torque (32.3 Nm) showed minimal change in marker localization.

Posterior pin removal had slightly more of an effect on marker coordinates than did anterior pin removal. With minimal, intermediate, and maximal torques applied in three different experiments following removal of the right

TABLE 1

*Shifts in marker coordinate localization with various combinations of pin or post removal and applied torque**

Pin	Torque (Nm)	Coordinate Deviation From Controls (mm)		
rt ant	6.5	x = 0.10	y = 0.34	z = 0.07
rt ant	11.3	x = 0.10	y = 0.14	z = 0.03
rt ant	27.8	x = 0.00	y = 0.14	z = 0.07
lt ant	6.5	x = 0.10	y = 0.14	z = 0.07
lt ant	11.3	x = 0.10	y = 0.24	z = 0.07
lt ant	27.8	x = 0.30	y = 0.24	z = 0.07
lt ant	32.3	x = 0.20	y = 0.64	z = 0.07
rt pos	6.5	x = 0.20	y = 0.44	z = 0.03
rt pos	11.3	x = 0.20	y = 0.44	z = 0.07
rt pos	27.8	x = 0.60	y = 0.24	z = 0.67
lt pos	6.5	x = 0.01	y = 0.66	z = 0.27
lt pos	11.3	x = 0.10	y = 0.76	z = 0.57
lt pos	27.8	x = 0.60	y = 0.76	z = 0.63
lt pos	32.3	x = 0.02	y = 1.16	z = 0.57

* ant = anterior; pos = posterior.

posterior pin, the coordinates deviated from the control values by 0.2, 0.2, and 0.6 mm, respectively, in the x plane; 0.44, 0.44, and 0.24 mm, respectively, in the y plane; and 0.03, 0.07, and 0.67 mm, respectively, in the z plane. As expected, the coordinate differences were largest when the right posterior pin was removed and the highest torque was applied (~ 27.8 Nm); the x plane movement of 0.60 mm and the z plane movement of 0.67 mm were both relatively minor. Left posterior pin removal caused the most significant coordinate changes when the highest torque (32.3 Nm) was applied. The y plane coordinates differed from the control values by 1.16 mm, whereas with the x plane and z plane differences of 0.02 and 0.57 mm, respectively, were observed. This Y-axis value was the only coordinate in any of the experiments that exceeded a 1-mm shift relative to the control values. A torque of 32.3 Nm is relatively high and is probably much more than would be generated by any patient (even awkwardly positioned for treatment). Even so, the localization difference was only approximately 1 mm. When torque was applied in the other three experiments after removal of the left posterior pin, the coordinates deviated from the control values by 0.1, 1.0, and 0.6 mm, respectively, in the x plane; 0.76, 0.76, and 0.76 mm, respectively, in the y plane; and 0.27, 0.57, and 0.63 mm, respectively, in the z plane.

Discussion

It was found that after removal of a single pin, the greatest changes in marker localization (1.2 mm) occurred when the highest torques were applied, particularly after a posterior pin has been removed. This implies that when a patient is awkwardly positioned during treatment and high torque forces are applied at the pin-skull interfaces, the dose distribution from a shot may be delivered up to 1.2 mm from its intended location if a pin has been removed to prevent a collision. More modest applied torque strengths did not significantly alter the positional target coordinates. This suggests that very accurate dose delivery is possible even with only three-pin fixation of the frame to the skull provided attempts are made to minimize forces at the pin-skull interface. This can be accomplished by positioning patients in such a way that forces on the frame during GKS are minimized. The significant finding of this study is the confirmation that three stereotactic headholder pins do indeed provide adequate stable positioning of the target volume under expected clinical conditions with low and moderate torque forces applied.

Conclusions

The results of this study suggest that in certain circumstances, GKS may be continued even if physical collisions or medical circumstances necessitate removal of one pin to complete the treatment.

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