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Pain experience using conventional *versus* angled anterior posts during stereotactic head frame placement for radiosurgery

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Abstract

Stereotactic frame placement for radiosurgery is assumed to be an uncomfortable experience. We developed angled anterior posts for the Leksell frame to avoid pin penetration of the temporalis muscle. This study aimed to determine the frequency of angled post requirement and quantify the patient pain experience from frame placement. We prospectively enrolled 63 patients undergoing radiosurgery. Angled posts were used when conventional post trajectory was posterior or within 3 mm of the superior temporal line to avoid temporalis muscle penetration. Pain scores (0 to 10) were collected prior to frame placement, immediately after frame placement, before radiosurgery, after radiosurgery, and a day after radiosurgery. A total of 63 patients were enrolled: 33 (48%) patients required angled posts. Women were significantly more likely to require angled posts than men (60.0% *versus* 33.3%, respectively; $p = 0.034$). Mean pain scores were very low, ranging from 0.33 to 2.23. There were no significant differences in pain outcomes between both groups at all time points. Stereotactic frame placement is not perceived to be a painful procedure. This information may be useful when counseling patients about the pain experience with frame application and the option of using angled anterior posts.

Keywords

Frame application; Leksell frame; Radiosurgery; Pain experience; Stereotactic frame

1. Introduction

Stereotactic radiosurgery is becoming an increasingly frequent treatment for brain tumors, vascular malformations, trigeminal neuralgia, and potentially even epilepsy [1–4]. Effective and safe use of radiosurgery depends on the delivery of a precise focus of ionizing radiation using image guidance. Therefore, accurate positioning and fixation of the frame onto the skull is essential for any stereotactic radiosurgery procedure. With the advent of frameless radiosurgery options such as CyberKnife (Accuray, Sunnyvale, CA, USA), many argue that

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one major advantage of the frameless system is to avoid the application of the rigid frame to the skull, which is thought to be painful by both treating physicians and patients. However, to our knowledge, no study has actually examined the pain experience of patients undergoing frame application during stereotactic radiosurgery.

Currently, the Leksell frame used in standard Gamma Knife (Elekta AB, Stockholm, Sweden) radiosurgery procedures is fixed to the outer table of the skull with four skull screws, two anterior and two posterior. When positioning the frame, depending on the size and shape of the patient's forehead, it is not uncommon for the anterior pins to contact the skull behind the superior temporal line (STL), penetrating the temporalis muscle [5]. This not only causes increased pain for the patients during pin insertion, but can also cause temporalis muscle swelling and increased post-procedural discomfort. Given the limitations of the standard frame, there was an opportunity to provide anterior posts with different fixed angles so that the trajectory of the front pins could be modified to avoid muscle penetration.

We have designed custom-made anterior bars for the Leksell frame with angled screw holes at 5, 10, and 15 degrees. These angled posts have been used in over 100 patients who have undergone stereotactic radiosurgery over the last 5 years [5]. However, objective data evaluating the frequency of requirement and the patient pain experience is necessary to further measure and characterize the benefits of using this new device in the clinical setting. Therefore, we performed a prospective study to quantify the patient pain experience from stereotactic frame placement and determine the frequency of use of angled anterior post.

2. Methods

This prospective study was formally approved by the University of California, San Francisco Committee of Human Research (IRB # 11-07134).

2.1. Patients

The eligibility of the cohort in this study was established by *a priori* inclusion and exclusion criteria. The study included all patients over 18 years of age who underwent Gamma Knife radiosurgery at the University of California, San Francisco, and were able to provide consent. Minors (18 years and younger) and patients with diminished capacity were not eligible to enroll in this study. The study period spanned a 12 month period starting in April 2012 and concluding in April 2013. Demographic and baseline variables were collected, being age at time of Gamma Knife treatment, sex, diagnosis, home narcotic use for pain, and prior craniotomy. For analytic purposes, diagnosis was categorized into four groups: metastasis, meningioma, schwannoma, and arteriovenous malformation/other. "Other" consisted of pituitary tumor, glioma, gliosarcoma, hemangioblastoma, and hemangiopericytoma.

2.2. Angled screw holes for anterior posts

The development of the custom angled screw holes for the anterior posts was described in detail by the senior author (M.W.M.) in a prior article [5]. In brief, the angled screw holes were drilled at 5, 10, and 15 degree angles (Fig. 1). The angles of the post are based on the angle of contact by the pin with the cranium (Fig. 2).

2.3. Frame positioning with conventional and angled anterior posts

All patients who underwent Gamma Knife radiosurgery and participated in this prospective study underwent an established protocol for placement of the stereotactic frame. The decision to use the angled anterior post depended on the proximity of the pin and STL as determined by the senior author. Prior to placement of the frame, the STL was marked on the skin on either side of the head. The frame was then positioned in a standard fashion. The trajectory and the point of contact of the anterior pins were marked on the skin (site #1). The distance from site #1 to the STL was measured in mm. If the marked pin site (site #1) was within 3 mm anterior to the STL or posterior to it, the angled posts (5, 10, or 15 degrees) were used instead of the standard post. The new trajectory and contact point of the angled post was marked on the skin (site #2) (Fig. 2). The anterior angled posts were then secured in a standard fashion after topical spray with ethyl chloride followed by subcutaneous and 15–20 cc of intradermal injection of 50:50 1% lidocaine/0.5% bupivacaine. No patients received intravenous fentanyl or midazolam prior to frame placement.

2.4. Pain assessment

A standardized pain assessment questionnaire was administered to all patients at multiple time points: immediately before frame fixation, immediately after frame fixation, before the Gamma Knife procedure, after the Gamma Knife procedure, and on the day following the procedure. A 10 point numeric pain scale was utilized to assess severity of pain.

2.5. Statistical analysis

First, demographics and baseline characteristics were compared between the conventional post group and angled post group to establish whether there were significant differences. Next, pain outcome scores at each of the time points were compared between the groups. Pain scores were analyzed through two modalities: as a continuous variable and as a categorical measure. Comparison of pain outcome as a continuous variable was reported as a mean with its associated standard deviation. For categorical analysis, pain outcomes scores were stratified into three distinct groups: low (pain score of 0–4), moderate (pain scores of 5–7), and severe (pain scores of 8–10). The chi-squared test was employed for categorical variables and outcomes, and in the case of continuous variables and outcomes, a two-way Student's *t*-test was performed for comparative purposes. A *p* value of 0.05 was set as the threshold of statistical significance. All statistical analysis was performed with the JMP statistical software (SAS; Cary, NC, USA).

3. Results

3.1. Patients

A total of 63 patients were enrolled in the study and all patients were included in the final analysis; 33 patients received the conventional post and 30 patients received the angled post (Table 1). Of the 63 patients, the mean age was 55.9 years old and 54.0% were male. There was no significant difference in age between the two groups (conventional *versus* angled: 55.6 *versus* 56.3, *p* = 0.836), but there was a significantly higher percentage of women in the angled post group compared to the conventional post group (60.0% *versus* 33.3%,

respectively; $p = 0.034$). The most common pathology treated in this cohort was metastasis (42.9%). Meningioma, schwannoma, and arteriovenous malformation/other made up 27.0%, 12.7%, and 17.5% of the other cases, respectively. Overall, 22.2% were on a regimen of narcotics prior to radiosurgery and 30.2% had undergone a prior craniotomy. There were no significant differences in diagnosis, narcotic use, and prevalence of prior craniotomy between the two groups (Table 1).

3.2. Pain experience

To assess the pain experience of patients undergoing stereotactic surgery, we assessed the pain level of each patient based on a 10 point score at the following time points: prior to frame placement, after frame placement, prior to radiosurgery, after radiosurgery, and the day after radiosurgery. For each time point, there was no significant difference in pain experience between the conventional anterior post and angled anterior post: prior to frame placement (0.55 *versus* 0.33, respectively; $p = 0.474$), after frame placement (0.94 *versus* 0.50, respectively; $p = 0.262$), prior to radiosurgery (0.88 *versus* 0.67, respectively; $p = 0.625$), after radiosurgery (1.55 *versus* 2.23, respectively; $p = 0.267$), and day after radiosurgery (1.32 *versus* 1.08, respectively; $p = 0.611$). It is noteworthy that mean pain scores were low for all time points, ranging from 0.33 to 2.23 out of 10. These findings are summarized in Table 2.

We stratified the pain scores as categorical variables: low (0–4), moderate (5–7), and severe (8–10). As seen, even with this analysis, there was no significant difference in pain outcomes between the two groups at each time point: prior to frame placement (Fig. 3A; $p = 0.944$), after frame placement (Fig. 3B; $p = 0.391$), prior to radiosurgery (Fig. 3C; $p = 0.546$), after radiosurgery (Fig. 3D; $p = 0.777$), and day after radiosurgery (Fig. 3E; $p = 0.317$).

4. Discussion

As the versatility of Gamma Knife radiosurgery continues to mature, it becomes even more important that stereotactic frame placement is safe, accurate, and comfortable for the patient. Advancement of radiosurgery technology has given rise to development of new frameless radiosurgery delivery systems. Proponents of these systems argue that one of the major advantages of the frameless system is to avoid the discomfort and anxiety associated with stereotactic frame placement; however, there has been no investigation of patient pain experience to our knowledge. Given these issues related to using a frame-based system, we felt it was necessary to objectively measure the user pain experience.

To our knowledge, this is the first prospective study to objectively assess the pain experience associated with stereotactic frame placement and compare an angled anterior post with a conventional anterior post. The standard approach to stereotactic frame placement is to use a conventional non-angled post to hold the frame in place. However, there is variability in forehead shape amongst patients such that a rigidly fixed angle for the trajectory of the front pins may not be suitable for all patients. The issue with the routine use of conventional posts is that in certain patients the pin is placed behind the STL and subsequently tightened into the temporalis muscle. This gives rise to two main issues: more pain at the fixation site and

risk for unsolicited moving or “creeping” of the pin as the pin contacts the outer table of the cranium at an oblique angle. In order to minimize pain and mitigate pin movement, angled posts were previously developed to avoid pin placement behind the STL.

From a prior study, we have demonstrated that an angled anterior post allows pins to maintain a perpendicular orientation of the fixation screw to the outer table of the cranium and thus allow the frame to preserve accuracy, maintain precision, and prevent shifting or “creeping” of the pin [5]. In that study, a cadaver model was also utilized to confirm the orthogonal trajectory of an angled anterior post to the outer table of the cranium. This study supplements our prior study by assessing the patient’s pain experience as we hypothesize that an angled anterior post can mitigate the unnecessary pain associated with temporalis fixation. Angled frontal bars were selected in 48% of patients to avoid muscle penetration. The findings from this study suggest that selection of the angled anterior post is effective in avoiding penetration of the temporalis muscle and reducing pain to similar levels as a conventional post.

Prior to frame placement, both groups had minimal pain at baseline, and only a minimal increase in pain immediately following placement of the stereotactic frame with either a conventional anterior post or angled anterior post. In addition, at other time points mean pain scores were well within the low range. According to these results, it appears stereotactic frame placement is a low-severity pain procedure. What makes this procedure well tolerated is the use of ethyl chloride spray prior to lidocaine/bupivacaine at the pin site before placement; this is evidenced by the minimal increase in pain as the effects of lidocaine wear out. None of our patients received intravenous fentanyl or midazolam that could affect their memory. Nonetheless, mean pain scores continued to be very low and only rarely did patients report severe pain. No patients were terminated from the study due to inability to tolerate the discomfort.

Importantly, both groups had similar pain outcomes at each time point of interest, which demonstrates that angled anterior posts are able to offer comparable pain experiences as conventional anterior posts. As intended by the study design, the reason for this is most likely because an angled anterior post allowed the pins to avoid fixation behind the STL and onto the temporalis muscle. This is important because pin placement over the temporalis can result in a lingering dull aching pain and post-procedural swelling the next day. Of the 63 patients enrolled in this study, about half of the patients required the angled post. Both groups were well matched in regards to narcotic use and prior craniotomy. However a large proportion of patients who required angled anterior posts were female and a larger proportion of patients who underwent conventional anterior post placement were male. This difference is likely reflective of the sexual dimorphism of head size and shape between males and females [6]. Therefore, attention to risk of fixating pins behind the STL needs to be taken into account when placing a stereotactic frame in females, and if available, consideration of using angled anterior posts to avoid temporalis involvement may offer the patient a better experience. Obviously standard posts were used when there was no risk of muscle penetration and angled posts were used to avoid muscle penetration, so the results are not unexpected.

The main limitation to this study is the lack of a positive control in which the anterior post and pin were directly fixated onto the temporalis muscle behind the STL. This would allow us to directly compare whether avoiding the temporalis is able to decrease a patient's pain experience. However given prior experience, we felt that it was unfair to subject patients to unnecessary pain. Another potential confounder was the use of lidocaine/bupivacaine around the site of pin fixation. As these are anesthetic agents, the patient does not appreciate noxious stimuli at the pin site. However, given that local anesthetic injection is the standard of care and is used in supplement to stereotactic frame placement in clinical practice, the findings of this study are directly applicable from this standpoint.

5. Conclusion

Stereotactic frame placement is a low severity pain procedure when the temporalis muscle is avoided. The use of angled anterior posts for stereotactic frame placement is safe and allows one to avoid temporalis muscle penetration. Practitioners of frame-based radiosurgery may be able to use this information to reassure patients that stereotactic frame placement is generally well tolerated with low levels of pain.

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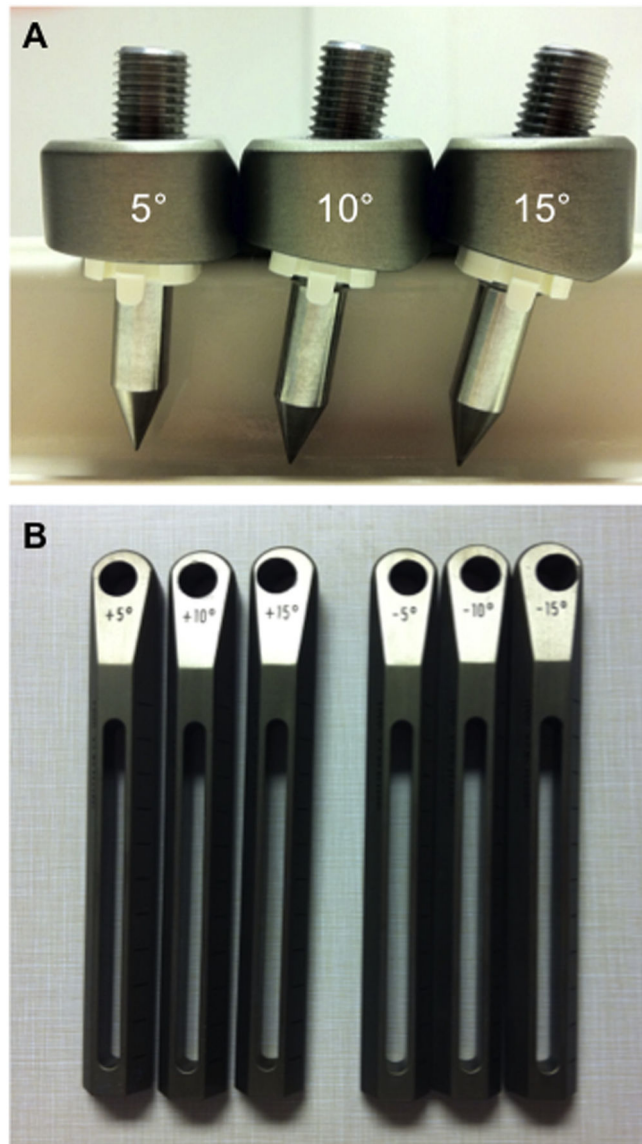


Fig. 1. (A) Close-up view of anterior posts with angled holes of 5 degrees, 10 degrees, and 15 degrees with pins in place. The progressive angulations of the pins can be easily appreciated. (B) Complete view of anterior posts with angled holes of both negative and positive degrees for the left and right side. (This figure is available in colour at <http://www.sciencedirect.com/>.)

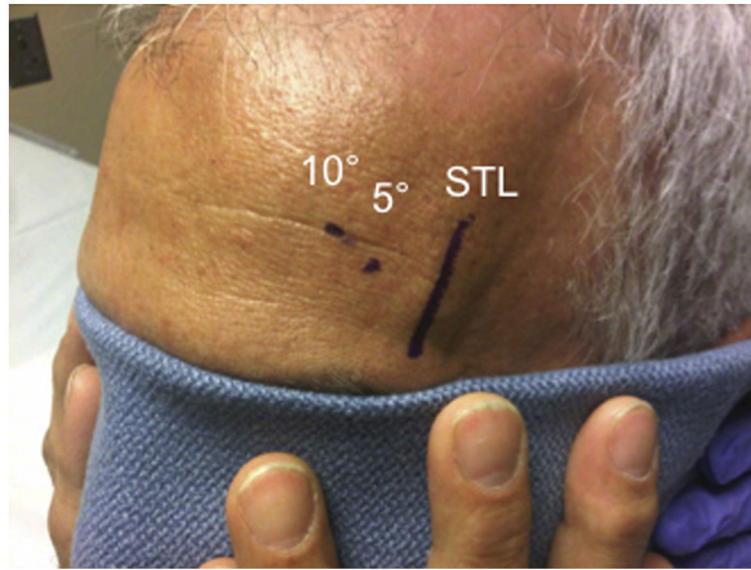


Fig. 2. Skin marks on a patient for 5 and 10 degree pin hole posts for a left-sided frame. The vertical line indicates the superior temporal line (STL). (This figure is available in colour at <http://www.sciencedirect.com/>.)

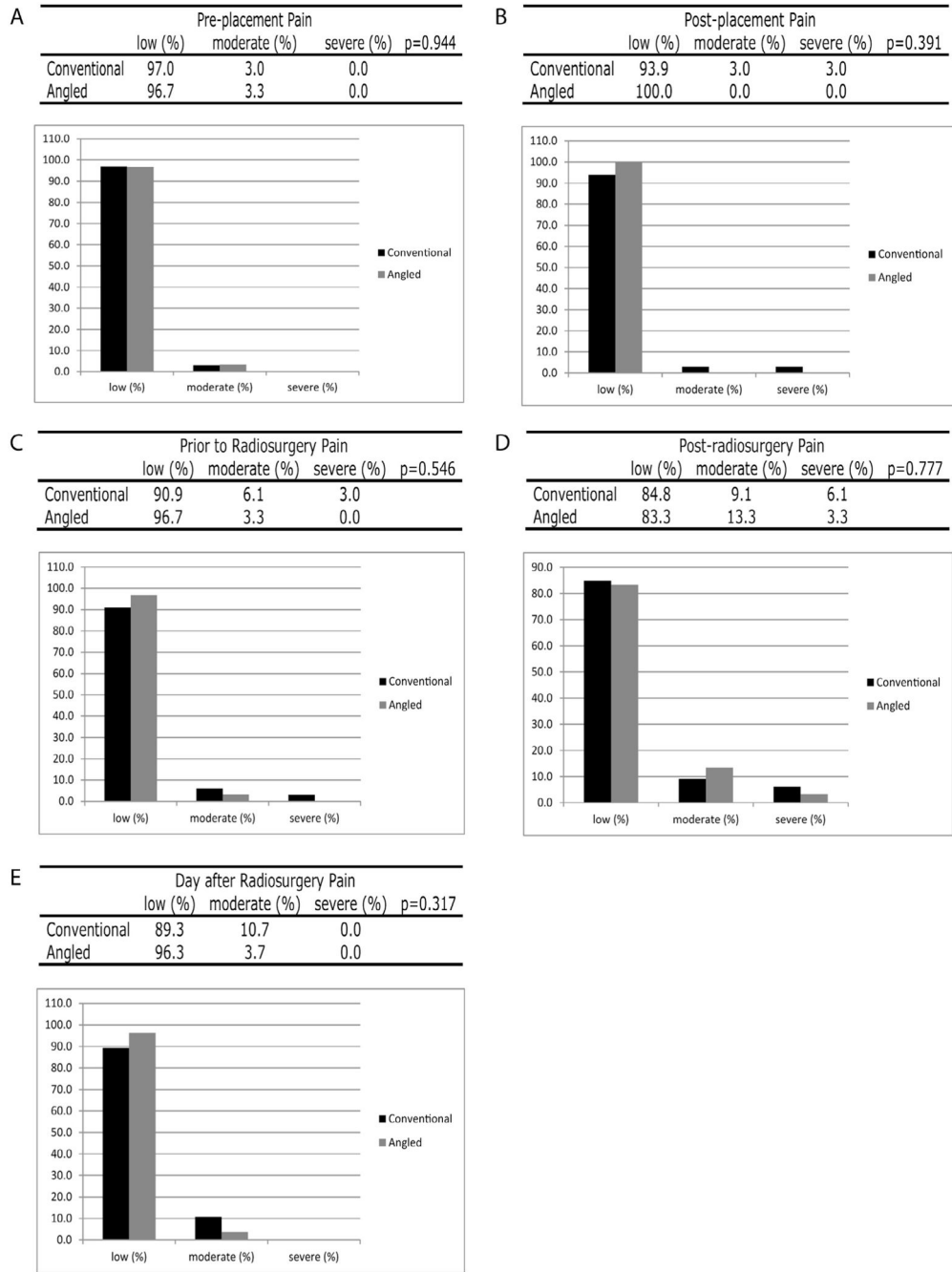


Fig. 3. Comparison of pain experiences among patients who received conventional and angled posts. Pain scores were stratified as low (0–4), moderate (5–7), and severe (8–10). There were no significant differences among the two groups for every time point measured, prior to pin placement (A), after pin placement (B), prior to radiosurgery (C), after radiosurgery (D), day after radiosurgery (E).

Table 1

Baseline characteristics among patients who received conventional and angled posts

	Total	Conventional posts	Angled posts	<i>p</i> value
Number of patients	63	33	30	–
Age (mean ± SD)	55.9 ± 13.2	55.6 ± 16.0	56.3 ± 9.6	0.836
Sex				0.034
Male	34 (54.0)	22 (66.7)	12 (40.0)	
Female	29 (46.0)	11 (33.3)	18 (60.0)	
Diagnosis				0.268
Metastasis	27 (42.9)	15 (45.5)	12 (40.0)	
Meningioma	17 (27.0)	6 (18.2)	11 (36.7)	
Schwannoma	8 (12.7)	4 (12.1)	4 (13.3)	
AVM/other	11 (17.5)	8 (24.2)	3 (10.0)	
Narcotic use	14 (22.2)	8 (24.2)	6 (20.0)	0.686
Prior craniotomy	19 (30.2)	12 (36.4)	7 (23.3)	0.260

Data are presented as n (%) unless otherwise stated.

AVM = arteriovenous malformation, SD = standard deviation.

Table 2

Comparison of experienced pain among patients who received conventional and angled posts

Pain score	Conventional posts	Angled posts	<i>p</i> value
Prior to frame placement	0.55 ± 1.30	0.33 ± 1.03	0.474
After frame placement	0.94 ± 1.94	0.50 ± 1.04	0.262
Prior to radiosurgery	0.88 ± 2.00	0.67 ± 1.40	0.625
After radiosurgery	1.55 ± 2.57	2.23 ± 2.25	0.267
Day after radiosurgery	1.32 ± 2.04	1.08 ± 1.52	0.611

Data are presented as mean ± standard deviation.

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