Frameless, Real-Time, Surface Imaging-Guided Radiosurgery: Clinical Outcomes for Brain Metastases

BACKGROUND: Frameless stereotactic radiosurgery is commonly used to treat intracranial metastases, but mask-based immobilization can be uncomfortable for patients. OBJECTIVE: To describe the clinical outcomes using a novel real-time, frameless, surface imaging–guided radiosurgery (SIG-RS) technique to treat brain metastases. METHODS: Data were prospectively gathered for 44 consecutive patients totaling 115 intracranial metastases treated with SIG-RS in a median of 1 fraction (range, 1-5) to a median dose of 20 Gy (range, 15-30 Gy). Local control, regional control, and overall survival were estimated by the Kaplan-Meier method. RESULTS: Median follow-up for all patients was 6.0 months (range, 0.3-21.6 months), with 31 of 44 (70%) deceased at the time of analysis. The 35 patients (80%) with follow-up imaging totaled 88 lesions evaluable for local control. Actuarial 6- and 12-month local control was 90% (95% confidence interval, 82-98) and 76% (95% confidence interval, 60-91), respectively. Regional failure was observed in 16 patients (46%). The median actuarial overall survival was 7.7 months (95% confidence interval, 5.7-9.7). Analysis of the subset of 22 patients (55 lesions) who received SIG-RS alone (no prior treatment) in a single fraction yielded comparable clinical outcomes. Grade 3 or greater toxicity occurred in 4 patients (9%). The median treatment time from beam on to beam off was 15 minutes (range, 3-36 minutes). CONCLUSION: SIG-RS for treating intracranial metastases can produce clinical outcomes comparable to those with conventional frame-based and frameless stereotactic radiosurgery techniques while providing greater patient comfort with an open-faced mask and fast treatment times.

KEY WORDS: Brain metastases, Frameless, Radiosurgery, Surface imaging

Stereotactic radiosurgery (SRS) is commonly used to treat patients with metastatic intracranial disease, either as standalone therapy or in conjunction with whole-brain radiation therapy (WBRT). By delivering very high doses of conformal radiation, SRS has been shown in several randomized trials and multi-institutional studies to provide highly effective local tumor control.\(^1\)\(^4\)

Initial implementations of SRS relied on a stereotactic head frame to provide rigid patient immobilization and target localization during treatment. Although this approach provided the necessary accuracy in treatment delivery,\(^5\) its disadvantages include patient discomfort and the impracticality of delivering fractionated therapy. More recently, several image-guided, frameless SRS systems have been developed, including the CyberKnife (Accuray Inc, Sunnyvale, California). These systems have in common the use of a custom-fitted patient mask for immobilization and patient position monitoring through serial x-rays and computed tomography (CT).

The accuracy of frameless SRS has been well established and is comparable in terms of radiation delivery to frame-based SRS.\(^6\)\(^-\)\(^8\) The
1 drawback of these systems is that treated patients are subjected to radiation exposure associated with serial x-rays or CTs. In keeping with the “as low as reasonably achievable” principle mandated by radiation regulatory agencies with regard to exposure to ionizing radiation,9,10 systems of real-time monitoring by externally attached infrared fiducials were developed for SRS. The first-generation technology attached the fiducials to a bite block formed to the dentition of the treated patient (Figure 1B). The 2 major limitations of this technology are the inability to treat patients with poor dentition and the potential movement of the fiducial at the site of attachment.11

To overcome these limitations, we explored technologies that used surface imaging-guided (SIG) systems for delivery of SRS. The SIG system implemented in the Radiation Oncology Department at our institution in late 2009 is AlignRT (VisionRT Ltd, London, UK). This system uses 3 ceiling-mounted nonionizing camera pods that capture facial landmarks of the patient and monitor any movement of these features during SRS delivery. We had previously demonstrated that this system provides excellent accuracy, with preclinical results comparable to those of cone-beam CT (CBCT) and infrared marker tracking.12-14 Here, we present the first clinical outcomes for patients with brain metastases treated at our institution using this novel real-time, frameless, nonionizing, SIG radiosurgery (SIG-RS) technique.

PATIENTS AND METHODS

Patient and Treatment Characteristics

With the approval of the local institutional review board, medical records were retrieved for patients ≥ 18 years of age who were consecutively treated with SIG-RS for intracranial metastases between December 2009 and May 2011 at our institution.

A total of 44 patients with 115 lesions are included in this report, with patient and treatment characteristics summarized in Table 1. The median largest tumor diameter was 9 mm (range, 2-43 mm). Most patients were treated in a single fraction except for 3 patients (7%) treated in 5 fractions and 2 patients (5%) who had their largest lesion treated in 5 fractions and their remaining metastases treated in a single fraction. The prescription dose was determined by the lesion size, with a median prescription dose of 20 Gy (range, 15-30 Gy) prescribed to the planning target volume (defined below). Six patients (14%) had failed previous WBRT before receiving SIG-RS; 2 of these 6 patients were unable to complete therapy: 1 patient required resection of the dominant metastasis for progressive neurological symptoms, and the other required hospital admission for cytomegalovirus mucositis and esophagitis. Five patients (11%) received combination therapy with surgical resection followed by SIG-RS to the resection cavity: 3 had gross total resection of a single metastatic lesion, and the remaining 2 had gross total resection of the dominant of multiple lesions.

Real-Time, Frameless SIG-RS

After giving informed consent, patients underwent fast spoiled gradient echo magnetic resonance imaging (MRI) with 1.25-mm axial slice intervals using a 3.0-T MRI (General Electric, Fairfield, Connecticut). For the initial patients, a customized immobilization system was designed with an expanding foam head mold (CDR Systems, Calgary, Alberta, Canada) that conformed to the patient’s head and was attached to the end of the table. This process also required cutting away of overflow material, trimming around the ears for comfort, and fixing forehead and mandible restraints with tape. For improved efficiency in subsequent patients, the head mold was replaced with an open-faced mask (CIVCO, Medical Solutions, Kalona, Iowa) with rigidity around the forehead and mandible for stability. This open-faced mask was paired with a custom SRS headrest (AccuForm, CIVCO Medical Solutions) that was added for improved patient comfort. With either immobilization scheme, the face was left exposed, both for patient comfort/convenience and for access to facial landmarks to be monitored during treatment by the surface imaging system. An example of the open-faced mask setup is shown in Figure 1A.

Patients then underwent simulation in a supine position with the head mold or open-faced mask using noncontrast CT (35-cm field of view, 512 × 512 pixel size, 1.25-mm slice interval). The MRI and the CT were then transferred to the treatment planning system, fused by use of a rigid auto-registration tool, and manually verified by the physicist and treating physician (J.D.L.). Planning was performed with Varian Eclipse software, version 8.9 (Varian Medical Systems, Palo Alto, California). The gross tumor volume and clinical target volume for each lesion were identical and were defined as the contrast-enhancing volume or resection cavity on axial MRIs. These volumes were contoured jointly by a neurosurgeon and a radiation oncologist. The planning target volume was then generated typically by adding a 1-mm margin to the clinical target volume.15 The body contour from the planning CT was reviewed for subsequent import into the surface imaging system for initial patient setup. Treatment plans were usually generated from multiple fields and dynamic multileaf collimators. Seven patients (16%) received therapy with volumetric modulated arc therapy; 1 patient (2%) received therapy in rotational arc beams with circular cone collimation. Patients with multiple lesions were treated at all targets simultaneously with intensity modulation and a single isocenter.16 Median minimum, median maximum, and median planning target dose to the planning target volume were 91% and 115% of the prescribed dose, respectively.

On the day of treatment, patient setup and monitoring were performed with AlignRT. The system consists of 3 ceiling-mounted nonionizing camera pods (2 lateral to and 1 at the foot of the treatment couch) that capture surface images to reconstruct the complete 3-dimensional surface of a selected region of interest of the patient. Each camera pod consists of 3 cameras (2 for stereovision, 1 for texture), a speckle flash unit for static imaging, and a speckle projector for dynamic imaging. The treatment plan and body contour were exported from the treatment planning system into AlignRT. The physicist then defined the region of interest to monitor, including the nose, zygomatic bones, eyes, forehead, and parts of the temporal bones (Figure 1C). An initial positioning is obtained by adjusting the patient under AlignRT guidance using the body contour from the planning CT as the reference image. The registration algorithm from AlignRT specifies errors with 6 df; the majority of our patients were treated on a couch without the capability for rotational adjustments beyond pitch, so manual repositioning was performed in the event of roll or yaw correctional requirement. After initial setup by AlignRT, onboard imaging kV planar imaging calibrated to 1 mm was acquired for assessment and repositioning, CBCT imaging was subsequently acquired as the gold standard for verification, with any shifts prompted by CBCT registration to the planning CT applied. A final reference image and region of interest were then reacquired by AlignRT for real-time intrafraction monitoring purposes.

Ten patients (23%) were treated on a TrueBeam linear accelerator (LINAC; Varian Medical Systems) with a maximum dose rate of 1400 MU/min, and the other 34 patients (77%) were treated on a Trilogy LINAC (Varian Medical Systems, Palo Alto, California).
Systems) with a maximum dose rate of 600 to 1000 MU/min. Treatment plans included noncoplanar fields in 33 cases (75%), requiring a median of 2 couch rotations (range, 0-10). These rotations were entered into AlignRT, and the appropriate surface contours were reconstructed and used as reference images for registration with the real-time surface image. During treatment delivery, therapists and the treating physician continually monitored patients with audio and visual monitors. Patient position was continuously monitored by AlignRT, with a manual (TrueBeam) or automatic (Trilogy) beam hold initiated if the motion exceeded the predefined translational threshold of 1 to 2 mm, determined on a case-by-case basis, and a rotational threshold of 1°. As previously reported, in instances of a beam hold, patients usually reverted quickly to a position within tolerance without external intervention, and

**FIGURE 1.** A, side view of the frameless, real-time, surface imaging-guided radiosurgery (SIG-RS) setup, including an open-faced mask. The open face leaves facial landmarks available for surface image monitoring and patient comfort, and the forehead and mandible rigidity provides stability. B, example of infrared fiducials attached to the bite block for localization and a rigid mask for immobilization used in stereotactic radiosurgery at our institution before SIG-RS. C, example of the region of interest monitored by the surface imaging system that included the nose, zygomatic bones, eyes, forehead, and parts of the temporal bones.
TABLE 1. Patient and Treatment Characteristics*  

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*SIG-RS, surface imaging-guided radiosurgery; WBRT, whole-brain radiotherapy  
†Patient completed 3 of 15 WBRT fractions.

Follow-up and Statistical Analysis

The follow-up period was defined as the time from the completion of radiation therapy to the most recent clinical evaluation or death. Patients were routinely seen 1 month after SIG-RS for a clinical examination, with subsequent radiographic follow-up and physician evaluation performed every 3 months. Treatment response was analyzed by local control, regional control, and overall survival. Local control was evaluated per brain metastasis and per patient and defined as the absence of disease progression, which was indicated by a radiographic increase > 20% of the sum of the largest diameters of a treated lesion. Regional control was evaluated per patient and defined as the absence of new intracranial metastatic disease occurring outside the treatment volume on radiographic examination and no clinical evidence of progression. Patients were censored at the time of most recent radiographic follow-up that showed absence of progression. Salvage therapy in the form of surgical resection, repeated SIG-RS, or WBRT was offered to patients with recurrent local disease or new intracranial disease.

Intracranial status was deemed unknown if no follow-up imaging had been obtained by the time of analysis. These patients were excluded from local and regional control analyses but were included in survival analysis. Overall survival from the date of diagnosis and local control and regional control from the date of treatment were estimated by the Kaplan-Meier method. Analysis was performed on the entire cohort of evaluable patients and the subset who received single-fraction SIG-RS alone without prior resection or WBRT and subsequent MRI follow-up. Differences in Kaplan-Meier curves were assessed by the log-rank test. A forward conditional multivariate analysis was performed by use of Cox regression modeling to assess factors predictive of overall survival.17 Mean treatment times with different LINACs were compared by use of Student t tests. All statistical analyses were performed with SPSS Statistics software, version 19 (Chicago, Illinois). Toxicity was graded according to the Radiation Therapy Oncology Group scale.16

RESULTS

Median follow-up for all patients was 6.0 months (range, 0.3-21.6 months); 31 of 44 patients (70%) died during the follow-up period. Median follow-up for the 13 surviving patients at the time of analysis was 9.8 months (range, 5.2-21.6 months). Nine patients (20%) were excluded from local and regional control analyses because of unknown intracranial status. Eight of these 9 patients (88%) were clinically evaluated at least once, with no evidence of grade 3 or greater toxicity. All 9 patients lost to radiographic follow-up were believed to have died of progression of systemic disease before the initial imaging, with a median survival of 2.7 months (range, 0.3-5.3 months) from the time of treatment. Radiographic follow-up was available for the remaining 35 patients (80%) and consisted of contrast-enhanced MRI (91%) and CT (9%).

Local Control

Of the 35 patients (88 lesions) with available follow-up imaging, 25 patients (71%) and 75 lesions (85%) did not show evidence of local progression. Median time to local failure of individual brain metastases was 7.2 months (range, 1.4-19.4 months) from the time of treatment. Actuarial 6- and 12-month local control of treated lesions was 90% (95% confidence interval [CI], 82-98) and 76% (95% CI, 60-91), respectively (Figure 2). Individual tumor size was significantly correlated with local control, with lesions ≤ 2.0 cm demonstrating better 6-month actuarial control (94% vs 77%; P = .02). Actuarial local control of treated patients was 82% (95% CI, 68-97) at 6 months and 70% (95% CI, 51-90) at 12 months. Patient demographics such as recursive partitioning analysis (RPA) class, number of lesions, patient age, and primary tumor type were not associated with significant differences in local control. Of the 10 patients with local failure, salvage therapy consisted of WBRT (4 patients), repeat SRS (2 patients), resection (1 patient), no further treatment (1 patient), and treatment to be determined (2 patients) given the discovery of progression at time of analysis.
Further analysis was performed on the subset of patients who underwent single-fraction SIG-RS alone (no prior WBRT or resection) with MRI follow-up. Of the 22 patients (55 lesions) who received single-fraction SIG-RS alone, 18 patients (82%) and 50 lesions (91%) did not show evidence of local recurrence. Actuarial local control of treated lesions was 92% (95% CI, 84-100) at both 6 and 12 months (Figure 3). Actuarial local control of treated patients was 89% (95% CI, 75-100) at both 6 and 12 months.

**Regional Control**

Regional brain failure was detected in 16 patients (46%), including 4 patients (11%) with simultaneous local and regional failure and 2 patients (6%) with local failure at a separate time. Median time to regional failure in evaluable patients was 5.3 months (range, 0.7-12.9 months) from the time of treatment. Actuarial 6- and 12-month regional control was 76% (95% CI, 60-91) and 41% (95% CI, 18-65), respectively (Figure 4). Salvage therapy for these new intracranial metastases consisted of WBRT (5 patients), SRS (5 patients), surgical resection (1 patient), resection followed by SRS (1 patient), and no further treatment (4 patients). Of the 4 patients who did not receive salvage therapy, 1 experienced primarily progressive systemic disease, 1 had both significant primary and intracranial progression, and 2 died soon after the identification of regional intracranial failure.

Regional failure for the single-fraction SIG-RS alone group occurred in 9 patients (41%). Actuarial regional control for this subset was 81% (95% CI, 63-98) and 53% (95% CI, 23-83%) at 6 and 12 months, respectively.

**Survival**

The median actuarial overall survival from the time of diagnosis was 7.7 months (95% CI, 5.7-9.7 months). The 6- and 12-month actuarial survival for all patients was 61% (95% CI, 47-76) and 38% (95% CI, 23-54), respectively (Figure 5). Multivariate analysis was performed to assess prognostic factors affecting overall survival, including age, sex, largest tumor diameter, primary tumor type, number of intracranial lesions, and RPA class, but none was statistically significant. The median actuarial overall survival was higher for RPA class II compared with RPA class III, but the difference was not statistically significant (8.2 vs 5.5 months; \( P = .51 \)).

For the single-fraction SIG-RS alone group, median overall survival was 12.4 months (95% CI, 7.7-17.1 months). Actuarial survival for this subset was 82% (95% CI, 65-98) and 51% (95% CI, 29-74) at 6 and 12 months, respectively.

**Treatment Times**

The median CBCT setup time for all patients was 11 minutes (range, 4-44 minutes). The median shifts calculated from CBCT after initial AlignRT setup were 2 mm (range, 0-5 mm), 1 mm (range, 0-6 mm), and 1 mm (range, 0-2 mm) in the superior-inferior,
anterior-posterior, and lateral directions, respectively. The maximum 6-mm shift was recorded for the initial patient and remains an outlier without a known reason but with hypotheses proposed previously. The median treatment time from initial beam on to final beam off was 15 minutes (range, 3-36 minutes). The average treatment time for the patients treated on a TrueBeam LINAC was shorter than that for the patients treated on a Trilogy LINAC (10.0 vs 17.6 minutes; \( P = .006 \)). Additional timing data for the first 23 patients, all treated on a Trilogy LINAC, were reported previously, including median initial surface imaging setup time with AlignRT of 13 minutes (range, 5-41 minutes), median total time from patient placement on the treatment table to final beam off of 38 minutes (range, 21-77 minutes), and 8 patients (35%) requiring repositioning.

**Toxicities**

Acute radiation toxicity of any grade occurred in 8 patients (18%), including 2 patients with grade 3 toxicities (5%) and no grade 4 or 5 toxicities. Two patients experienced acute grade 1 toxicity of fatigue and dizziness. Grade 2 events were found in 3 patients, including falls, headaches resolving with steroids, and weakness. Acute grade 3 toxicities included 1 patient admitted for headache, nausea, and vomiting after seizure activity and another patient who experienced hemorrhage and seizure after treatment. Late toxicity occurred in 2 patients (5%). One patient who required late admission for aphasia (grade 3) had previously experienced acute grade 2 falls with SIG-RS and radionecrosis with prior WBRT. The other late toxicity was an admission for seizure, headache, and lethargy secondary to radionecrosis (grade 4).

**DISCUSSION**

The new treatment technique SIG-RS allows improved patient comfort by providing minimal immobilization while avoiding the use of an invasive head frame, a closed mask, or a bite-block–based system. Efficient delivery of image-guided radiosurgical treatment is achieved without detriment to the accuracy/precision of treatment, treatment times, or clinical outcomes. Although feasibility studies were previously published, the clinical efficacy of SIG-RS remains an unanswered question. Here, we present the first series to document the clinical outcomes of SIG-RS in 44 patients with brain metastases (115 treated lesions) treated with this novel technique.

In evaluating our SIG-RS system, we focused on local control. Our finding of a 12-month actuarial local control rate of 76% is comparable to previous frame-based and frameless studies reporting Kaplan-Meier data that showed local control rates of 71% to 89% and 76% to 80%, respectively (Table 2). The majority of patients (77%) in this study received SIG-RS alone, without prior resection or WBRT that could influence local control rates. An additional end point that was analyzed was overall survival. The 12-month actuarial overall survival in this study was 38%, which also is comparable to previously published...
results of 23% to 54% survival for patients treated with frame-based or frameless SRS methods (Table 2).

Subset analysis of patients who received SIG-RS alone in a single fraction with subsequent MRI follow-up showed local control, regional control, and overall survival comparable to those of the overall cohort. The sample size was too small for definitive conclusion of the impact of prior resection or WBRT on clinical outcomes.

Potential benefits of this new treatment technique over previous approaches include improved patient comfort because of the open-face setup and improved feasibility of fractionated therapy. Although no objective measure of patient comfort was recorded, patients did not report discomfort, and some were comfortable enough to fall asleep during treatment. Additionally, real-time intrafraction motion monitoring is performed directly on the actual patient instead of a fiducial marker. The surface imaging system provides nonionizing, real-time monitoring and is not dependent on patient instead of a fiducial marker. The surface imaging system includes the limitations inherent in such a study design, including bias in determining local failures and treatment toxicities. We attempted to mitigate these limitations by having 2 authors (H.P., J.D.L.) independently review all available medical records to document possible failures and toxicities. Additionally, not all patients underwent follow-up imaging for local and regional control documentation and were thus excluded from that component of the analysis.

### CONCLUSION

Results of this study suggest that SIG-RS for treating intracranial metastases can produce clinical outcomes comparable to those for conventional frame-based and frameless SRS techniques while providing greater patient comfort with an open-faced mask and maintaining fast treatment times. Although long-term outcomes data for SIG-RS will continue to mature, this study has provided encouraging initial clinical outcomes such that the system will continue to be used for all intracranial radiosurgery treatments at our institution.

### Disclosure

The authors have no personal financial or institutional interest in any of the drugs, materials, or devices described in this article.

### REFERENCES


**COMMENTS**

This is a very nice retrospective study of 44 patients with 115 intracranial metastases treated with a frameless radiosurgery approach. “Frameless” implies treatment without the rigid immobilization of a neurosurgical frame. There are many commercial systems that allow frameless radiosurgery, some of which allow real-time monitoring of the patient during treatment. All frameless radiosurgery platforms use the same basic principles of immobilization and targeting accuracy, which facilitate the delivery of large doses of radiation, with a sharp dose falloff outside the target volume. Although all frameless radiosurgery systems need to minimize patient movement, those that do not use real-time monitoring of the patient need to ensure that the patient cannot appreciably move (within the accepted error limits of radiosurgery) after the initial setup.

This study describes the outcomes of patients treated with a commercial system, AlignRT, that enables real-time monitoring of the facial surface. Immobilization was achieved with a head mold or open-faced mask, which the authors describe as more comfortable for patients than a tight-fitting mask molded to the face. Targeting accuracy was achieved before treatment with an onboard imaging system (kV planar imaging or cone-beam computed tomography) and during treatment through the use of real-time monitoring of the facial surface. Because this was a retrospective study, there was heterogeneity in the patient characteristics, patient treatment (ie, some underwent whole-brain radiation, some targets were the surgical cavity of a resected brain metastasis), prescribed dose, and number of fractions; additionally, the immobilization technique and radiation planning and delivery system changed as technology was upgraded. However, the AlignRT commercial system was used in all patients. Interestingly, all patients (including those with multiple targets) were treated with a single isocenter technique. Advantages of the AlignRT system include the use of nonionizing imaging, the ability to reproducibly set up edentulous patients (ie, no bite block required), and the imaging of an entire surface (vs use of a limited number of markers/sensors). A potential disadvantage of using surface anatomy (vs bony anatomy or fiducials in the treatment of extracranial targets) is the assumption that the surface accurate reflects internal anatomy. This is of much less concern in treating cranial targets; although some defined regions of interest such as the nose and eyes can potentially move and the facial muscles overlying the rigid facial bones can move, this is of much less concern compared with treating extracranial targets. Furthermore, the alignment of all patients in this study was verified with onboard imaging, and the surface anatomy registration was adjusted to this.

The local control and survival outcomes are comparable to those published in the literature. Indeed, this would be expected if real-time monitoring facilitated accurate setup (in addition to the approach of single isocenter radiosurgery). Obviously, one cannot make definitive outcomes comparisons from a relatively small study such as this with an entire body of literature, particularly for brain metastases patients, in whom outcomes are dependent on a multitude of variables (giving rise to several prognostic

Hidefumi Aoyama
Niigata, Japan

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indicator scores). Nevertheless, the authors did an admirable job of describing how a novel real-time monitoring technique can be used to treat brain metastases, resulting in acceptable outcomes. In basic terms, this approach “works.” It is important to note that the Patients and Methods section describes a multidisciplinary team involving radiation oncologists, neurosurgeons, physicists, and radiation therapists. It also describes a formalized quality assurance approach in the verification of patient positioning. These components are critical for any radiosurgery program, particularly in adopting new technologies.

Michael Milano
Rochester, New York

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