

## Publications about Novalis®

### **Radiosurgical Treatment for Ewing's Sarcoma of the Lumbar Spine**

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**Published in:** SPINE, Volume 27, Number 21, pp E471–E475

**Study Design:** Case report.

**Objectives:** The objective of this study was to document the long-term follow-up of a single case.

**Summary of Background Data:** Radiosurgery is potentially a useful therapeutic option for spinal tumors. The authors present the unusual case of a patient with recurrent extraosseous Ewing's sarcoma of the lumbar spine, who experienced excellent clinical, radiographic, and oncologic response without complications after treatment with dedicated Novalis Shaped Beam Radiosurgery (BrainLab, Inc.).

**Methods:** Observational.

**Results:** We observed excellent clinical and oncologic control at 1-year posttreatment.

**Conclusion:** Radiosurgery may be a valuable treatment option for recurrent spinal tumors.

**[Key words: Ewing's sarcoma, spine, Novalis Shaped Beam Radiosurgery]**

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### **CLINICAL USE OF STEREOSCOPIC X-RAY POSITIONING OF PATIENTS TREATED WITH CONFORMAL RADIOTHERAPY FOR PROSTATE CANCER**

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**Publ. in:** Int. J. Radiation Oncology Biol. Phys., Vol. 54, No. 3, pp. 948–952, November 2002

**Purpose:** To evaluate accuracy and time requirements of a stereoscopic X-ray–based positioning system in patients receiving conformal radiotherapy to the prostate.

**Methods and Materials:** Setup errors of the isocenter with regard to the bony pelvis were measured by means of orthogonal verification films and compared to conventional positioning (using skin drawings and lasers) and infrared marker (IR) based positioning in each of 261 treatments. In each direction, the random error represents the standard deviation and the systematic error the absolute value of the mean position. Time measurements were done in 75 treatments.

**Results:** Random errors with the X-ray positioning system in the anteroposterior (AP), lateral, and longitudinal direction were (average  $\pm$  1 standard deviation)  $2 \pm 0.6$  mm,  $1.7 \pm 0.6$  mm, and  $2.4 \pm 0.7$  mm. The corresponding values of conventional as well as IR positioning were significantly higher ( $p < 0.01$ ). Systematic errors for X-ray positioning were  $1.1 \pm 1.2$  mm AP,  $0.6 \pm 0.5$  mm laterally, and  $1.5 \pm 1.6$  mm longitudinally. Conventional and IR marker-based positioning showed significantly larger systematic errors AP and laterally, but longitudinally, the difference was not significant. Depending on the axis looked at, errors of  $\geq 5$  mm occurred in 2%–14% of treatments after X-ray positioning, 13%–29% using IR markers, and 28%–53% with conventional positioning. Total linac time for one treatment session was 14 min 51 s  $\pm$  4 min 18 s, half of which was used for the X-ray-assisted positioning procedure.

**Conclusion:** X-ray-assisted patient positioning significantly improves setup accuracy, at the cost of an increased treatment time.

**Patient positioning, Conformal radiotherapy, Prostate cancer.**

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## A TECHNIQUE FOR INTENSITY-MODULATED SPINAL RADIOSURGERY

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**Scientific Presentation AAPM 2002, Montreal**

### Material & Method

A new technique of performing spinal radiosurgery has been developed. The highly conformal single dose is delivered using a dedicated Novalis shaped beam surgery unit with a built-in micro-multileaf collimator. Each patient is simulated in the supine position using an AcQsim CT simulator with a body-fix immobilization device.

A variety of different treatment plans are developed, but the most common plan is the use of 7 co-plannar intensity-modulated beams to minimize radiation to critical organs such as spinal cord.

An automatic localization device based on infrared and video cameras is used to guide the initial patient setup. And two keV x-ray imaging systems are used to identify potential deviations from the planned isocenter. A total of 30 patients with tumors around the spinal cord have been treated using this technique with a single prescription dose ranging from 6 Gy to 12 Gy.

### Results

The final verification images indicated that the average isocenter deviation from the planned isocenter is within 2 mm. The phantom verification of isocenter dose shown that the average measured isocenter dose is within 3% of the planned isocenter dose. Film dose measurement illustrated good agreement of above 50% isodose lines between planned and measured results.

Preliminary experience shows that precision delivery of high dose radiation could be achieved to the planned target volume while keeping the dose to the critical organs within the tolerable limits.

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## DOSIMETRIC CHARACTERISTICS OF NOVALIS SHAPED BEAM SURGERY UNIT

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**Published in:** Medical Physics -- August 2002 -- Volume 29, Issue 8, pp. 1729-1738

The dosimetric characteristics of a new dedicated radiosurgical treatment unit are systematically measured in terms of its percent depth dose, beam profile, and relative scatter factor. High-resolution diode detector, mini-ion-chamber detector, and conventional Kodak XV films are used to measure dosimetric data for a range of field sizes from 6×6 mm to 100×100 mm. The effects of collimator size, micro-multileaf collimator shape, and detector type on the dosimetric data are investigated. Results indicate that, with careful design, accurate dosimetric data could be acquired using either a dedicated diode detector or a mini-ion-chamber detector, and film detector. Special attention is required when measuring dosimetric data for small field sizes such as 6×6 mm.

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## AUTOMATED PATIENT SET-UP USING STEREOSCOPIC X-RAY IMAGES: CLINICAL VALIDATION

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### Abstract ESTRO 2002, Prague

With the introduction of a dedicated linac for stereotactic radiosurgery (NOVALIS: BrainLAB AG) in March 2000, a feasibility study had been initiated for treatment of extracranial targets such as the prostate and liver metastasis. The limited field size (10×10 cm at isocenter) emphasized the need for reliable positioning and reduction of treatment margins required in conformal and intensity modulated radiation therapy. A prototype X-ray imaging tool has been integrated with a real-time infrared-tracking device allowing automated positioning of the patient from outside the treatment room, based on either automated fusion of the actual treatment images with DRRs representing the desired position or matching implanted radio-opaque markers. Phantom studies showed an overall 3-dimensional set-up accuracy (for combinations of both translational and rotational set-up errors) of 0.4 mm (SD: 0.9 mm) for the automated fusion of DRRs, and 0.3 mm (SD: 0.4 mm) when using implanted markers for set-up. A clinical validation of the X-ray fusion tool has been performed with portal film on 15 patients (261 treatment sessions) with prostate cancer, yielding a highly significant improvement in patient set-up along the 3 principal axes compared to other positioning methods (i.e. conventional patient set-up based on room lasers and set-up with a commercially available infrared tracking device – ExacTrac1.0, BrainLAB, AG) and resulted in a 2- to 3-fold reduction of moderately large ( $\geq 5$  mm) and large errors ( $\geq 10$  mm). The random errors (the standard deviation of measure set-up errors) using X-ray positioning in the anteroposterior, lateral and longitudinal direction were 2.0 mm (SD: 0.6 mm), 1.7 mm (SD: 0.6 mm) and 2.4 mm (SD: 0.7 mm) respectively. Whereas systematic errors of 1.1 mm (SD: 1.2 mm) (anteroposterior), 0.6 mm (SD: 0.5 mm) (lateral) and 1.5 mm (SD: 1.6 mm) (longitudinal) have been observed. Total linac time in this study (patient entering treatment room to patient leaving treatment room) was 14'51' (SD: 4'18'). The X-ray assisted patient positioning required 7'54' (SD: 3'43'). The stereoscopic X-ray imaging device integrated with the real-time infrared tracking device represents a fully automated positioning tool allowing for the geometrical accuracy that is required for conformal radiation therapy of abdominal and pelvic lesions, within an acceptable time-frame. Based on these studies the system has been clinically released as the ExacTrac2 / NOVALIS BODY by BrainLAB AG.

Part of this work has been supported financially by BrainLAB AG.

## Considerations on treatment efficiency of different conformal radiation therapy techniques for prostate cancer

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**Published in:** Radiotherapy and Oncology 63 (2002) 27–36Abstract

**Background and purpose:** To evaluate the treatment efficiency of different conformal radiation therapy techniques in prostate cancer.

**Materials and methods:** Three major classes of intensity-modulated radiation therapy (IMRT) delivery as well as a conformal rotation technique have been evaluated: sequential tomotherapy, dynamic multileaf collimation (DMLC) with conventional MLC, DMLC with miniMLC and dynamic field shaping arc. Treatment planning for the IMRT techniques has been performed with inverse planning. Forward planning was used for the dynamic arc technique. The four techniques have been compared to treat two different prostate cases with a conservative target dose of 70 Gy: a convex shaped target volume and one containing concavities formed by the bladder and rectum. Cumulative dose volume histograms, tumor control probability and normal tissue complication probability, conformity index and dose heterogeneity, and finally efficiency of treatment delivery have been evaluated.

**Results:** For the convex shaped target, all treatment modalities met the desired treatment goals, although the conventional MLC delivered more dose to the bladder. Compared to the dynamic arc modality, both tomotherapy and the conventional MLC technique needed a tenfold higher number of monitor units per target dose, and the miniMLC a twofold higher number. The same trend has been observed for the concave target, yet the dynamic arc did not meet the desired dose reduction for the rectum. The miniMLC configuration represented the best compromise for both targets with respect to treatment goals and delivery efficiency. Sequential tomotherapy performed adequately with respect to conformity at the cost of efficiency.

**Conclusions:** Together with conformity and delivery efficiency the shape of the target should be considered as an important parameter in the selection of the treatment modality.

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## Dose broadening due to target position variability during fractionated breath-held radiation therapy

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**Published in:** Medical Physics -- July 2002 -- Volume 29, Issue 7, pp. 1430-1437

**Abstract:** Recent advances in Stereotactic Radiosurgery/Conformal Radiotherapy have made it possible to deliver surgically precise radiation therapy to small lesions while preserving the surrounding tissue. However, because of physiologic motion, the application of conformal radiotherapy to extra-cranial tumors is, at present, geared toward slowing the progression of disease rather than obtaining a cure.

At the University of Rochester, we are investigating the use of patient breath-holding to reduce respiratory-derived motion in fractional radiotherapy. The primary targeting problem then becomes the small variation in tumor location over repeated breath-holds. This paper describes the effects of residual target position uncertainty on the dose distribution observed by small extra-cranial tumors and their neighboring tissues during fractional radiation treatment using breath holding. We employ two computational methods to study these effects: numerical analysis via Monte Carlo simulation and analytical computation using three-dimensional convolution. These methods are demonstrated on a 2-arc, 10-fraction treatment plan used to treat a representative lung tumor in a human subject. In the same

human subject, the variability in position of a representative lung tumor was measured over repeated end-expiration breath-holds using volumetric imaging. For the 7×7×10 mm margin used to treat this 12 mm diameter tumor and the measured target position variability, we demonstrated that the entire tumor volume was irradiated to at least 48 Gy—well above the tumoricidal threshold. The advantages, in terms of minimizing the volume of surrounding lung tissue that is radiated to high dose during treatment, of using end-expiration breath holding compared with end-inspiration breath-holding are demonstrated using representative tumor size and position variability parameters. It is hoped that these results will ultimately lead to improved, if not curative, treatment for small (5–20 mm diameter) lung, liver, and other extra-cranial lesions.

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### Initial Clinical Results of Stereotactic Radiotherapy for the Treatment of Craniopharyngiomas

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**Published in:** Technology in Cancer Research & Treatment; ISSN 1533-0346; Volume 1, Number 1, February (2002)

**Abstract:** The efficacy and toxicity of stereotactic radiotherapy (SRT) for the treatment of craniopharyngioma has been retrospectively evaluated in 16 patients. The median tumor diameter was 2.8 cm (range 1.5–6.1) and the median tumor volume was 7.7 cc (range 0.7–62.8). SRT was delivered to a single isocenter using a dedicated 6 MV linear accelerator to patients immobilized with a relocatable stereotactic head frame. The three-year actuarial overall survival was 93% and the rate of survival free of any imaging evidence of progressive disease was 75%. The three-year actuarial survival rates free of solid tumor growth or cyst enlargement were 94% and 81% respectively. Our results suggest that SRT is a safe and effective treatment approach for patients with craniopharyngioma. Long-term follow-up is required to determine whether the normal tissue-sparing inherent with SRT results in reduction of the neurocognitive effects of conventional radiotherapy for craniopharyngioma. SRT can be delivered to craniopharyngioma that may be difficult to treat with stereotactic radiosurgery due to proximity of the optic chiasm. Further clinical experience is necessary to determine the clinical utility of beam shaping in the setting of SRT.

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### STEREOTACTIC RADIOSURGERY USING A DEDICATED LINEAR ACCELERATOR AND GAMMA UNIT: A COMPARISON STUDY

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**Abstract Publ. in:** Radiotherapy and Oncology 58(suppl 1): 433-434, 2001.

**Purpose:** Stereotactic radiosurgery has become an accepted modality in the treatment of primary and metastatic brain tumors, benign brain tumors, and certain other neurological disorders. The purpose of this work is to investigate the characteristics of a new linear accelerator dedicated for stereotactic radiosurgery (Novalis), to compare the dosimetric characteristics to that of a traditional gamma unit, and to demonstrate the capabilities of the device in targeting cranial neoplasms.

**Methods:** A phantom designed to hold film for dosimetry purposes was constructed from square pieces of solid water. A hole was drilled through the center of the phantom to accommodate a needle. The phantom assembly was rigidly affixed within a Leksell stereotactic frame in such a way that the plane of the film intersected the axial plane at a small angle. With a needle inserted into the hole, 1 mm axial CT scans were obtained of the phantom. Treatment plans, utilizing the 3 and 8 mm collimators and multiple arcs in the case of the Novalis, and 4 and 8 mm helmets of the Gamma Knife, were performed using the point of intersection of the needle and film plane as an isocenter. Film was inserted and the phantom was positioned and treated as per each treatment plan. The 50% width, left and right penumbral width (80% to 20%) and offset from planned isocenter were determined from each film with the aid of a commercial dosimetry system.

**Results:** Measured offset from planned isocenter was similar on both units and indicated sub-millimeter targeting precision. For the Novalis 3 mm collimator, measured FWHM ranged from 3.5 to 4.0 mm while the penumbra ranged from 2.06 to 2.61 mm. For the 4 mm gamma unit helmet, ranges for the FWHM and penumbra were 5.7 to 6.6 mm and 2.26 to 3.48 mm respectively. For the 8 mm Novalis collimator, the FWHM and penumbra were 8.90 to 10.30 mm and 2.78 to 5.22 mm respectively, while similar range in measurements for the gamma unit were 12.00 to 13.60 mm and 3.13 to 6.44 mm.

**Conclusions:** Both dedicated radiosurgery units demonstrated acceptable targeting and dosimetric characteristics. The targeting accuracy of the Novalis was also confirmed independently in an animal model.

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## **DYNAMIC ARC RADIOSURGERY FIELD SHAPING: A COMPARISON WITH STATIC FIELD CONFORMAL AND NONCOPLANAR CIRCULAR ARCS**

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**Publ. in:** International Journal of Radiation Oncology\*Biophysics, 49:5 : 1481-1491

**Purpose:** Recent advances in field-shaping technology and linac multileaf collimator (MLC) integration have resulted in new approaches to performing stereotactic radiosurgery. We present a modeling study comparing the absolute dose distributions from three radiosurgery delivery techniques: a conventional approach utilizing noncoplanar circular arcs, a static field conformal approach, and a dynamic arc field-shaping approach. In the latter, the MLC leaves more in a continuous fashion, conforming to the beam's-eye-view projection of the target at every increment along the path of an arc.

**Methods and Materials:** For the analysis, we devised a simulated target consisting of three overlapping spheres. This was chosen because it offered a straightforward planning approach for all three techniques, primarily the multiple isocenter approach. In addition, three representative cases were selected from the prior radiosurgery experience. These range in increasing size, from 0.50 to 9.79 cm<sup>3</sup>, and in complexity, requiring from 3 isocenters to 16 in the case of circular arcs. In each situation, the goals were twofold: (1) to cover the entire volume with as high an appropriate isodose level (90% in the case of the conformal and dynamic arc techniques, 50% in the case of circular collimators) while (2) minimizing the dose to normal brain and where applicable, any adjacent radiation-sensitive structures. Because of the latter requirement, a single isocenter circular arc approach was ruled out for the analysis.

**Results:** In the case of large or irregularly shaped lesions, the circular arc technique requires multiple isocenters, producing a high level of dose heterogeneity within the target volume. Both the static field and dynamic arc conformal techniques, as with all single isocenter approaches, produce a highly homogeneous dose throughout the target region. For a given large dose, peripheral dose is decreased as additional beams or arc degrees are added with either of the conformal approaches. Dose-volume histogram analysis evaluating the peripheral dose shows that, in many cases, dose to surrounding structures can be reduced through the use of a conformal static or dynamic arc approach over the conventional multiple isocenter, circular arc techniques.

**Conclusions:** Dynamic arc shaping is an efficient and effective method for accurately delivering a homogeneous target dose while simultaneously minimizing peripheral dose in radiosurgery applications.

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### **Conformal radiosurgery using a dedicated linac and micro multileaf collimator**

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The use of multileaf collimators (MLC) in conventional radiotherapy delivery has become common. MLCs provide a convenient and efficient means of shaping square fields, this allowing additional normal tissue to be excluded from the treatment volume. In contrast, stereotactic radiosurgery for brain tumors has traditionally been performed using circular radiation fields. Use of multiple isocenters is necessary to conform the dose closely to the target in the event that the target has an irregular shape. This results in increasing dose inhomogeneity within the target volume which may or may not be desired. Furthermore, the use of multiple isocenters adds to the overall treatment time. Recently the use of sample-shaped fields has been proposed for use in stereotactic radiosurgery applications [1-3].

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### **First World Experience with Novalis Stereotactic Radiosurgery and Radiotherapy**

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**Publ. in:** published in the Book of Proceedings of the 12th World Congress of Neurosurgery, September 2000.

**Purpose:** To evaluate the initial experience with a dedicated linear accelerator with integrated beam shaping capabilities (Novalis) for radiosurgery regarding development of complications and early treatment failure.

**Methods and Materials:** During the period of December 1997 to March 2001, 725 patients were treated with the Novalis at the University of California Los Angeles. Females corresponded to 52.6% (382) of the patients and males 47.3% (343). Ages ranged from 5-88 years (mean 52.4). Single fraction radiosurgery was the treatment of choice in 492 patients (67.9%) and fractionated stereotactic radiotherapy in 233 (32.1%). In the single dose group, treatment doses ranged from 10 to 30 Gy (mean; 16.5 Gy) and for functional cases from 70 to 200 Gy (mean: 90.7Gy). Patients submitted to fractionate stereotactic radiotherapy received doses between 9.0 to 75,6 Gy (mean: 41.2 Gy).

**Results:** The reduced time of treatment of complex radiosurgical lesions and the highly homogeneous dose to the lesion volume compares favorably to other radiosurgical techniques available. Remarkable response of lesions and symptoms has been observed. Complications needing surgical intervention occurred in 08 patients (1.5%).

**Conclusions:** This study validates the use in the clinical setting of the Novalis system. Long-term follow-up is necessary to compare the statistical accomplishments of this technology to the traditional ways of applying radiosurgery.