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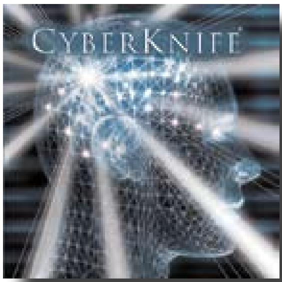

Your Partner in Good Health

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IN THIS ISSUE

CyberKnife Robotic Radiosurgery

Offers Non-invasive Treatment, Precision Delivery

Traditional radiosurgery – or stereotactic radiosurgery – has been used to treat tumors in the head for more than 30 years. It utilizes high doses of radiation precisely targeted at the site of the tumor and typically delivered in one treatment session. The treatment relies on a rigid metal frame that is fixed to a patient's skull, immobilizing the head so that damage to the healthy tissue surrounding the tumor is minimized when the radiation is delivered.

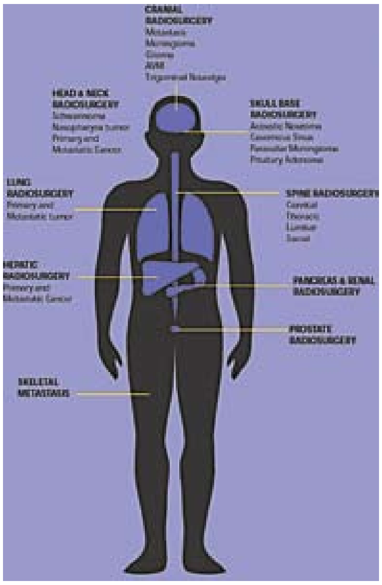
In contrast to traditional radiosurgery, robotic radiosurgery combines image guidance technology and computer controlled robotics, which enable the system to deliver high doses of radiation without a metal head frame while maintaining sub-millimeter accuracy. The CyberKnife System is designed to continuously track, detect and correct for tumor and patient movement throughout the treatment. Because of this accuracy, other areas of the body become treatable with robotic radiosurgery, such as the spine, lung, prostate, liver and pancreas. Because it is non-invasive, treatments can be delivered in single or multiple fractions at the patient's convenience. The CyberKnife System provides an additional option to many patients diagnosed with previously inoperable or surgically complex tumors.

The CyberKnife Robotic Radiosurgery System takes advantage of intelligent robotics to enable the effective treatment of tumors anywhere in the body. To date, more than 20,000 patients have been treated with the CyberKnife System, and currently more than 50 percent of all CyberKnife procedures in the United States are extracranial.

What is Radiosurgery?

Stereotactic radiosurgery (SRS) combines the principles of 3-D target localization, with multiple cross-fired beams from a high-energy radiation source to precisely irradiate an abnormal lesion within a patient's body. This technique allows maximally aggressive dosing of the target, while normal surrounding tissue receives lower, non-injurious doses of radiation. The ideal objective is the ablation or destruction of the targeted area without damaging any normal tissue outside of the defined target area. Stereotactic radiosurgery differs from conventional radiotherapy in several ways. The efficacy of radiotherapy depends primarily on the greater sensitivity of tumor cells to radiation relative to normal brain tissue. With all forms of standard radiotherapy, the spatial accuracy with which the treatment is focused on the tumor is a secondary concern; normal tissues are protected by administering the radiation dose during multiple sessions (fractions) daily for a period of a few to several weeks.

In contrast, radiosurgery, by its very definition, requires much greater targeting accuracy. With SRS, normal tissues are protected by both selectively targeting only the abnormal lesion, and using cross-firing techniques to minimize the exposure of the adjacent anatomy. Because highly destructive doses of radiation are used, any normal structures (such as nerves or sensitive areas of the brain) within the targeted volume are subject to damage as well. Typically, SRS is administered in one to five daily fractions over consecutive days. Nearly all SRS is given on an outpatient basis without the need for anesthesia.



Treatment is usually well-tolerated, and only very rarely interferes with a patient's quality of life.

Stereotactic radiosurgery has been used for more than 30 years to treat benign and malignant tumors, vascular malformations and other disorders of the brain with minimal invasiveness. To date, more than 200,000 patients have been treated worldwide with radiosurgery. The success of SRS is based, to a large extent, on the use of a multidisciplinary approach, which requires close interaction between surgeons, radiation oncologists, medical oncologists, physicists, diagnostic radiologists, technicians and nurses. This specialized team is responsible for the selection of appropriate patients for SRS, treatment delivery and long-term follow-up.

What are the differences between the common radiosurgery technologies?

Several SRS systems are available for the treatment of patients. The most widely used SRS devices include: cobalt-sourced systems (Gamma Knife), modified linear accelerators and the CyberKnife. All of these devices, if properly operated, are capable of delivering the desired radiation dose to a designated target. However, for certain clinical situations, there can be important differences between these devices, which for some patients may have a significant impact on clinical outcome.

Cobalt-Sourced Systems (Gamma Knife)

The first radiosurgical device was conceived and developed in the 1950s by Professor Lars Leksell at the Karolinska Institute in Stockholm, Sweden. His work culminated in the development of the Gamma Knife (Elekta Inc.), which was used to treat patients beginning in 1968. This device is capable of precisely irradiating a small intracranial target with gamma ray photons. The treated lesion is targeted and the patient's head immobilized through the use of an external metal frame attached to the skull by four screws. A large, helmet-shaped device with 201 separate, fixed "holes" or ports allows the radiation emitted by discrete radioactive cobalt-60 sources to enter the patient's head in small beams that converge on the designated target. The Gamma Knife is designed to treat intracranial targets only.

Modified Linear Accelerator Systems

An alternative to the Gamma Knife was developed in the mid-1980s and utilized the conventional linear accelerators (linac) that are commonplace in most large hospitals. By combining a series of small modifications to the radiation delivery mechanism of the linac with specialized planning software, it is possible to do many types of brain radiosurgery. There are both dedicated and non-dedicated linac-based radiosurgery devices. Dedicated linac systems are used solely for radiosurgery treatment. In contrast, non-dedicated systems are the daily workhorses for conventional radiation therapy departments that can also be temporarily modified to perform radiosurgery. Compared to the latter multi-purpose linacs, dedicated systems tend to be more carefully calibrated for spatial accuracy and optimized for radiosurgical efficiency. Unlike the radioactive cobalt-based Gamma Knife, linac-based systems use X-ray beams generated from a linear accelerator. As a result, these

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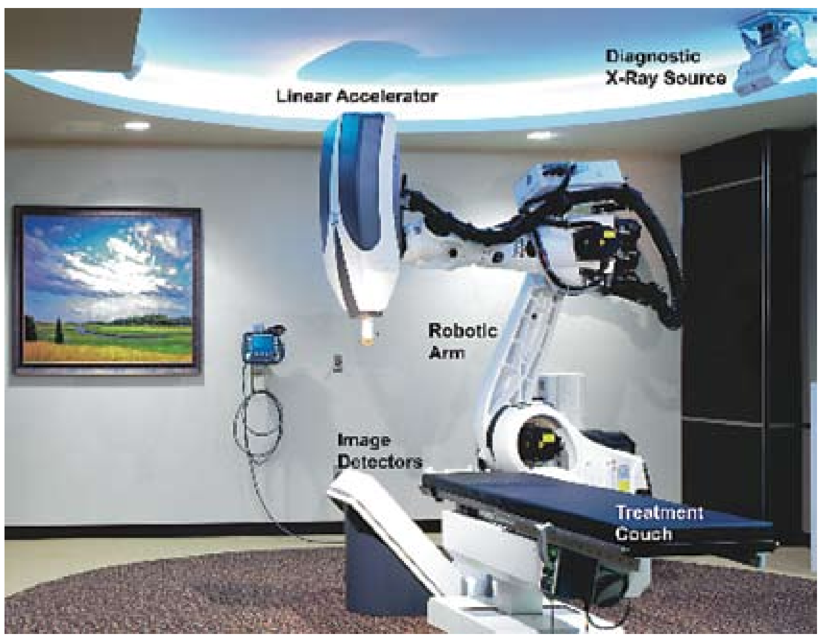

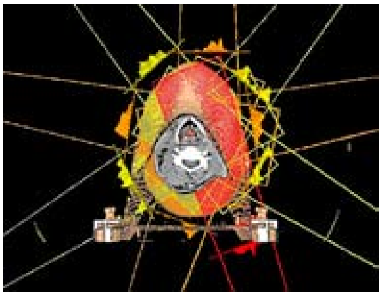

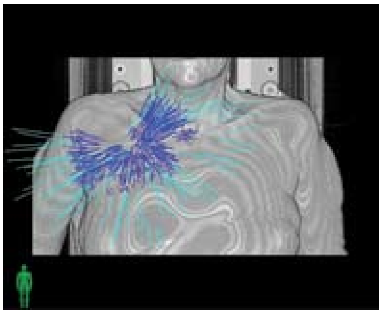

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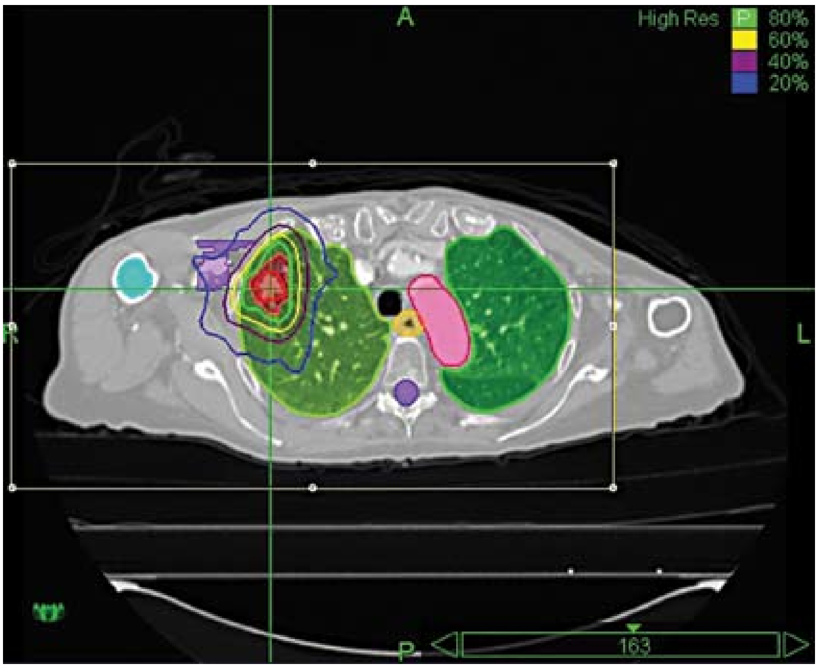
devices do not require or generate any radioactive material. When treating brain tumors with linac radiosurgery, a metal head frame is attached to the patient's skull and used to precisely target the radiation beam. Common brand names for modified linacs include X-Knife (Radionics Inc.).

Shaped Beam Systems

The recent development of IMRT or Intensity Modulated Radiation Therapy has added another dimension to multi-fraction radiation therapy. These linac-based technologies use computer-controlled "beam-shaping" to do a better job of conforming the radiation dose to the shape of the tumor or other lesion. This form of advanced radiation therapy can be utilized at virtually any location in the body. IMRT technology enables a mechanical device (called a multi-leaf collimator) that is typically attached to most modern medical linear accelerators, to dynamically reshape the outlines and intensity of the radiation field during cancer treatment. When combined with sophisticated planning software, IMRT fits the dose of radiation to a target much better than conventional radiation therapy, and thereby minimizes the volume of surrounding normal tissue that is injured by treatment. While it appears that IMRT may produce fewer side effects than conventional radiation therapy, IMRT is not as spatially precise as radiosurgery. Because of this imprecision, a full course of IMRT treatment is typically administered over multiple treatment sessions (typically 20-30+). Common brand names include X-Knife (Radionics) and Novalis (Brain Lab).

CyberKnife System

The CyberKnife System is an SRS system utilizing contemporary technology that is designed to be the most accurate and flexible tool available for aggressive therapeutic irradiation. The CyberKnife was designed to address the limitations of frame-based SRS systems and expands the application of radiosurgery to sites outside of the head. It is the only system to incorporate a miniature linear accelerator mounted on a flexible, robotic arm. An image-guidance system that can track target location during treatment also enables the CyberKnife to offer superior targeting accuracy without the need for the invasive head frame. While Gamma Knife and linac-based systems can perform radiosurgery in the brain, true radiosurgery for areas outside of the brain is difficult, if not impossible to perform with these systems.

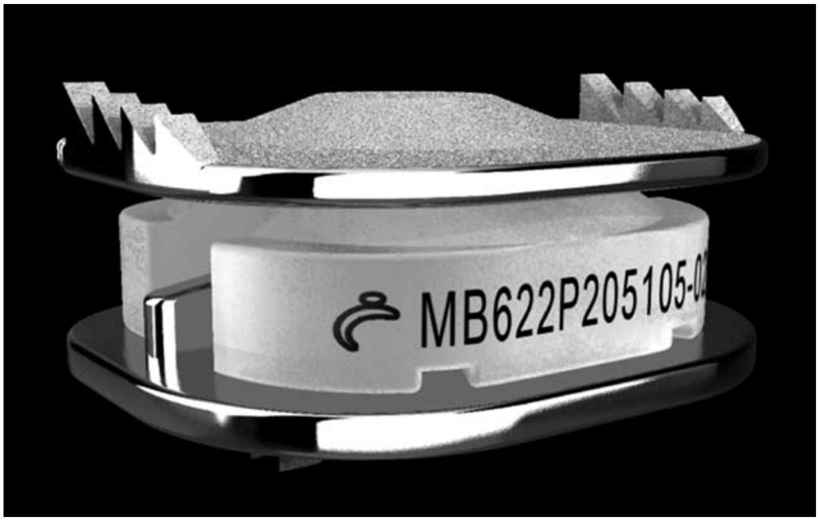


For More Information

about the CyberKnife Program, go online to www.brainandspine.net/cyberknife/physicians. To arrange for a patient consultation or referral, contact the Brain and Spine Center at Brackenridge Hospital at (512) 324-8060. Ron Wilson, MD, is medical director of the CyberKnife Program. He can be reached at **rwilson@seton.org**.

Brain &Spine Center

Launches LDR Clinical Trial



The country's only two-level Cervical Artificial Disc Clinical Trial is underway at the Brain and Spine Center at Brackenridge Hospital

The purpose of the Mobi-C® device and other artificial cervical discs is to restore normal biomechanical function after disc excision, provide pain relief and, at the same time, avoid subsequent degeneration at adjacent levels. The mobile insert articulates between the superior and inferior spinal plates, which allow for various degrees of mobility that include six degrees of freedom (two translational, three rotational and one axial). The amount of translation that is provided in both the X and Y directions is ± 1mm. The amount of controlled rotation around the X and Y axes is ±10°.

Objectives of the Investigation

The purpose of this investigation is to establish the safety and effectiveness of the LDR Spine Mobi-C® Cervical Disc Prosthesis, which is an anterior cervical interbody mechanical device. The primary objective of the study is to evaluate the safety and effectiveness of the investigational device as compared to the control in the treatment of patients with symptomatic degenerative disc disease with radiculopathy or myeloradiculopathy at one or two adjacent levels.

The study is a prospective, randomized, multi-center, concurrently controlled investigation in which the study device will be compared to the control treatment consisting of conventional anterior cervical discectomy and fusion in accordance with the Smith-Robinson procedure. The study will be randomized in a 2-1 ratio.

Because the two-level replacement study will be conducted concurrently with the one-level replacement study, all training cases will be nonrandomized to the one-level replacement study. The total proposed sample size for the two-level replacement study is 327 subjects (218 Study/109 Control).

Number of Replacement Levels	Number of Random (Study:Control)	Study	Number of Patients Control	**Total**
One	2:1	184	82	**266**
Two	2:1	218	109	**327**
Total One- and Two-Level Replacement Studies		402	191	**593**

Duration of the Investigation

Patients will be followed post-operatively at six weeks and three, six, 12, 18 and 24 months. After 24 months, patients will continue to be followed annually. Accounting for time required to enroll patients in the investigation, the total study duration is estimated to be five years.

Patient Eligibility Criteria

The inclusion criteria for patients are:

- 18-69 years old.

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- Diagnosis of radiculopathy or myeloradiculopathy of the cervical spine with pain, paresthesia or paralysis in a specific nerve root distribution C3 through C7, including at least one of the following:
  - Neck and/or arm pain (at least 30mm on the 100mm VAS scale);
  - Decreased muscle strength of at least one level on the clinical evaluation 0 to 5 scale;
  - Abnormal sensation including hyperesthesia or hypoesthesia; and/or
  - Abnormal reflexes.
- Radiographically determined pathology at one or two adjacent level(s) to be treated correlating to primary symptoms, including at least one of the following:
  - Decreased disc height on radiography, CT or MRI in comparison to a normal adjacent disc;
  - Degenerative spondylosis on CT or MRI; and/or
  - Disc herniation on CT or MRI.
- Symptomatic at one or two adjacent levels from C3 to C7.
- Neck Disability Index score of ≥15/50 or ≥30 percent.
- Unresponsive to non-operative, conservative treatment (rest, heat, electrotherapy, physical therapy, chiropractic care and analgesics).
- Appropriate treatment for using an anterior surgical approach, including having no prior surgery at the operative level and no prior cervical fusion procedure at any level.

Principal Investigators

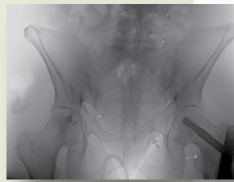
The principal investigators for the study are Daniel Peterson, MD, and John Stokes, MD, neurosurgeons with the Brain and Spine Center at Brackenridge Hospital.

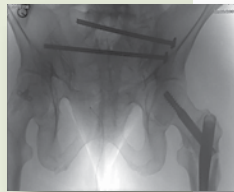
For more information about the study, contact the Brain and Spine Center at (512) 324-7772.

Case Study

Presented by the Orthopaedic Traumatologists at Brackenridge Hospital

Orthopaedic Trauma Patient Regains Strength, Mobility





▲ PREOP PELVIS (TOP) AND POSTOP PELVIS

Patient History

A 55-year-old female presented to the Brackenridge Emergency Department as an unrestrained backseat passenger involved in a motor vehicle collision. Initial evaluation revealed multiple skeletal injuries, including fractures of the pelvis, left femur, left elbow, left proximal humerus, right proximal humerus, right wrist and a right hip dislocation, as well as multiple rib fractures and an extraperitoneal bladder rupture.

Treatment

The patient was taken to the operating room on the day of her presentation for closed reduction of the right hip dislocation and fixation of the left femur fracture with an intramedullary nail. During the next few days, surgical procedures were performed to treat the remainder of her skeletal injuries, including percutaneus iliosacral screw placement to stabilize the posterior pelvic ring injury. The patient also underwent open reduction and internal fixation with plates and screws to fixate the left distal humerus and left olecranon fractures, left proximal humerus fracture, right proximal humerus fracture and right distal radius fracture.

Hospital Course

Physical therapy was initiated in the early post-operative period allowing the patient to mobilize from bed to chair, as well as begin active and passive range-of-motion exercises for her upper and lower extremities. No casting was necessary due to the fixation techniques utilized. The patient was discharged to home (out of state) after less than two weeks in the hospital. At last report, she has continued to regain strength and mobility.

Discussion

Multiple-injury patients present a challenge to health care providers, requiring coordination among various specialists to best treat these patients. During the past thirty years, orthopaedic traumatology has evolved as a subspecialty within orthopaedic surgery, facilitating the timely care of patients with multiple injuries. Improved implants and surgical techniques have allowed orthopaedic trauma surgeons to operatively treat fractures with less-invasive techniques, limiting the need for immobilization after surgery. In this case, insertion of the iliosacral screws was performed using real-time X-ray and one-centimeter incisions. The plates and screws used to stabilize the proximal humerus, elbow and wrist fractures consist of "locking screw" technology, providing the most secure fixation periarticular fractures available.

For more information, contact Austin Skeletal Trauma Specialists David Laverty, MD, and Drake Borer, MD, at (512) 391-1751.