Innovative Bone Anchor Set to Reach Market in 2006
By Isador Lieberman, M.D., M.B.A.

The Merlot Bone Anchor, an innovative corkscrew-like medical implant created and refined over the last eight years in the Cleveland Clinic’s Spine Research Laboratory (a testing site for experimental equipment and devices), is going to challenge and advance the way orthopaedic specialists correct spinal fractures; treat degenerative disorders or deformities, such as scoliosis; perform spinal reconstruction and intervertebral body stabilization; and mend joint and bone fractures.

The curlicue anchor, which was “discovered” with the pop of a cork after a particularly frustrating day in the lab, does what the rods, screws and bolts now being used in bone fixation/stabilization surgery do, but it does it better and faster. And, because of the size of the device and its ease of implantation, the Merlot Bone Anchor does it with smaller surgical incisions.

Originally, the anchor had one “coil.” Research showed that two – placed directly across from each other to create a double-helix effect – were more efficacious. The double-helix anchor drills into bone the same way a traditional bone screw does, but instead of coring out bone (and needing to be secured with a bolt), it spirals into the bone’s matrix. This minimizes damage to the bone and the need for additional hardware. It also maximizes bone-to-metal surface area “grip,” which helps the anchor resist pull-out and torque—Merlot anchors begin to fail at around 80 pounds of pressure, while standard devices begin to fail at 10 pounds, the two biggest problems with currently used implants.

In addition, the anchor’s coils, acting like springs, adapt to the modulus of the bone, creating a bone-coil bond that strengthens the bone and transmits force – as the patient sits, stands, walks, bends, etc. – equally throughout the bone.

The Merlot anchor may be manufactured from a variety of different materials: poly-carbonates, carbon fibers, the “memory metal” nitinol, titanium and cobalt chrome alloys. The anchor’s composition, function and size are tailored to a patient’s needs. By varying the materials used to make the anchor, the length and pitch (distance between) of the device’s coils, and where the coils are attached to the platform, the anchor can be used in the surgical treatment of curvature and other anomalies of the spine, as a supplement to existing implants, and for hip fractures, which are increasingly seen in the aging population. In addition, laboratory evidence suggests the implant has potential for use with long bone re-pairs and dental implants.

The Merlot anchor an easy implant to add to their surgical armamentarium. While the design of the Merlot anchor is revolutionary, the surgical techniques for implanting the device, which is on the fast-track to get FDA approval by the third quarter of 2006, are similar to those used with current devices. And, because the device was designed to take advantage of minimally invasive/endoscopic surgical techniques, its use means patients will be spending less time in the hospital, healing more quickly, and getting through physical rehabilitation faster.

Dr. Isador Lieberman is a member of the Cleveland Clinic Spine Institute with joint appointments in the departments of Orthopaedic Surgery and Neurological Surgery. The executive director of the Minimally Invasive Surgery Center and the director of the Center for Advanced Skills Training, he specializes in minimally invasive surgery for scoliosis, spine tumors and osteoporosis. He can be reached at 216/445-2743 or at lieberi@ccf.org.

Chairman’s Report
By Joseph P. Iannotti, M.D., Ph.D.,
Chairman, Department of Orthopaedic Surgery

The Department of Orthopaedic Surgery at The Cleveland Clinic continues to enjoy its No. 5 ranking in the U.S. News & World Report’s annual survey of America’s Best Hospitals. The department has 60 full-time physicians, practicing at 13 sites throughout northeastern Ohio. The staff includes 49 operative staff (44 orthopaedic surgeons and five operative podiatrists) and 11 non-operative staff (five primary care physicians, four orthopaedists and three podiatrists).

In 2004, the department recorded 240,000 outpatient visits and more than 12,000 surgical procedures (Figure 1). Our surgical volumes reflect the trend in orthopaedics on a national level. Our department performed nearly 3,000 hip and knee replacements, with an increasing number and percentage of revision cases over the last five years (Figure 2). The number of shoulder arthroplasties performed has substantially increased (Figure 3), and the number and proportion of arthroscopic procedures, particularly for shoulder instability and rotator cuff repair, has increased dramatically (Figure 4). The utility of minimally invasive hip arthroscopy to treat labral tears and mechanical derangement is demonstrated by the growing number of procedures performed (Figure 5).

The number and proportion of cases performed at the Cleveland Clinic’s outpatient surgery centers have increased over the last several years (Figure 6). Our Pediatric Orthopaedic Section has a growing clinical activity and now has five full-time pediatric orthopaedic surgeons. Our Sports Medicine Section has 11 physicians and surgeons, and more than 91 physical therapists and sports trainers. Our Sports Health surgeons performed 440 ACL procedures, which include multiple knee ligament reconstructions (Figure 7), and the Sports Health team cared for athletes from 42 high schools, four colleges and four professional sports teams.

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Are orthopaedic surgeons ready for the practical challenges our profession will face in the next 25 years? According to the National Institute on Aging, by 2030 the number of Americans aged 65 to 74 will increase from 19 million to an estimated 36 million people, and the number of people aged 75 to 84 will grow from 16 million to 25 million. Consequently, the population of patients with degenerative arthritis will continue double-digit growth well into the foreseeable future. This will mean equivalent growth in the demand for arthroplasty, which will exert considerable pressure on the orthopaedic operating room. In response, the orthopaedic OR of the future must be designed to handle a high volume of arthroplasty surgeries with more speed, precision and consistency in quality, outcomes, safety and value.

To begin planning for these changes, The Cleveland Clinic has partnered with Stryker Corporation (Kalamazoo, Mich.) to model the orthopaedic OR of the future, on location at The Cleveland Clinic. This technology and commercialization agreement provides a unique opportunity to evaluate, learn and make further changes that will prepare us for the future. The Cleveland Clinic-Stryker team identified over 480 distinct processes that take place between the time the patient is scheduled for surgery until discharge. The next objective is to create the most efficient and effective model for arthroplasty, then construct the OR to test it.

Job analysis, a technique borrowed from industry, will determine the most efficient arrangement for supplies, equipment and personnel in the room. Through physical changes in room layout and process changes in tasks related to arthroplasty, we believe we can significantly reduce cycle time for the OR. Ultimately, every orthopaedic OR should be able to handle one more case per day, boosting efficiency and cutting costs.

In the preliminary planning, The Cleveland Clinic-Stryker team identified over 480 distinct processes that take place between the time the patient is scheduled for surgery until discharge. The next objective is to create the most efficient and effective model for arthroplasty, then construct the OR to test it.

What will that model look like? Standardization in processes and procedures will be the key to meeting the increased operative demand. Standardizing virtually every aspect of arthroplasty, from scheduling through discharge, allows for better planning and cost management; any variances that occur can be dealt with more easily. Standardization will take many forms. For example, every arthroplasty OR will be set up identically, down to the items in the drawers. The arthroplasty procedure itself is being dissected into discrete tasks, and each task, such as how a nurse hands an instrument to the surgeon, will be described in detail.

The floor in the OR of the future will be clear of equipment and supplies, and unnecessary barriers, cabinets and storage areas will be removed or redesigned. Patient X-rays will be displayed on monitors located throughout the room. Surgical navigation will allow for more accurate implant placement. The stock room will run on a computerized inventory system to ensure supply availability and stock rotation. Job analysis, a technique borrowed from industry, will determine the most efficient arrangement for supplies, equipment and personnel in the room. Planning is underway to accommodate the advanced technology that will be an essential component of the new orthopaedic OR. Surgeons will have the capability of using computer simulation to visualize the path of an instrument before making an incision. The first of three prototype ORs based on this model is under construction. The Cleveland Clinic-Stryker team plan to have the prototype completed for the October Medical Innovation Summit here at The Cleveland Clinic, which this year showcases orthopaedic surgery. We consider this room the first step in an ongoing evolution in which we will continue to evaluate, learn and make further changes that will prepare us for the future.

Dr. Jonathan Schaffer is an orthopaedic surgeon with special interest in arthroplasty and orthopaedic research. He also is the Managing Director of e-Cleveland Clinic. He can be reached at 216/444-8960 or by e-mail at schaffj@ccf.org.
Cleveland Clinic orthopaedic surgeons currently have more than two dozen orthopaedic technologies or devices in the commercialization pipeline through CCF Innovations, the Clinic’s technology commercialization arm. Established in 2006, CCF Innovations assists physicians in translating therapies, devices and diagnostics into medical products through spin-off companies, licensees and equity partners. Orthopaedic surgery is one of two specialty areas that work hand in hand with CCF Innovations and has been one of the most fruitful in terms of number of products. Cleveland Clinic orthopaedic surgeons who have launched products through CCF innovations attribute their success to working in an environment that promotes the interchange of ideas and experience between the clinical and basic science arenas. By bringing new ideas to market and developing an efficient distribution system for them, CCF Innovations’ goal is to benefit the largest number of patients possible. CCF Innovations develops a team that includes physicians and their inventions, deal makers, patent attorneys and corporate partners to turn an invention into a product. CCF Innovations has a successful record in achieving this, and the Cleveland Clinic’s ratio of inventions to dollar of research money is among the highest in the United States.

Novel Hydrogel Technology Moves Closer Toward Commercialization

By Anthony Calabro, Ph.D.

Localized damage to the articular cartilage surface as a result of a sports or work-related injury can be severely disabling and lead to osteoarthritis. We have developed novel glycosaminoglycan-based (GAG-based) hydrogels for use as biomaterials in a wide variety of tissue engineering and repair applications including repair of localized cartilage defects in the field of orthopaedic surgery.

In developing these novel hydrogels, we have shifted the paradigm used in most tissue engineering research from a cell-based approach to a biomaterial-based approach that relies heavily on the insights provided by nature’s own macromolecular design for a healthy, functional articular cartilage. Articular cartilage is the resilient load-bearing tissue that forms the articulating surfaces of diarthrodial joints. The cartilage functions to absorb mechanical shock and spread applied load onto subchondral bone. Normal articular cartilage exhibits its viscoelastic properties, as well as its ability to resist deformation and absorb compressive loads, principally as a result of creating a macromolecular network with low porosity and a high density of fixed negative charges. The macromolecular properties of such a macromolecular network manifest themselves in a concentration-dependent fashion through the well-known mechanisms associated with Donnan, electrorepulsion and stress-shielding effects.

In articular cartilage, this is accomplished by the fixation of COO- and SO42- groups on resident hyaluronan (HA) and chondroitin sulfate (CS) chains at the high concentration of these GAGs normally found in cartilage (50-100 mg/ml).

In designing biomaterials for cartilage repair, our laboratory has taken the approach of using the same molecular scaffold materials (e.g., HA, CS) already proved to produce a mechanically functional natural cartilage matrix. The use of these GAGs as scaffold materials, when formed into the proper 3-D architecture, assures a biologically compatible product that reproduces the desired mechanical function of cartilage.

A novel enzyme-driven method for cross-linking these GAGs into solid matrices has been developed by our laboratory, which: 1) preserves sufficient negative-charge density on the GAGs to recreate both Donnan and electrorepulsion effects and, thus, the mechanical properties of natural cartilage. The use of these GAGs as scaffold materials, when formed into the proper 3-D architecture, assures a biologically compatible product that reproduces the desired mechanical function of cartilage.

Beyond orthopaedics, potential applications for BioGel also have been identified in plastic surgery, ophthalmology, otolaryngology, cardiology and gastroenterology. One of the most versatile inventions to come out of Orthopaedic Surgery, the BioGel technology eventually may be licensed to other companies for specific applications.

Orthopaedic surgeons Isador Lieberman, M.D., currently have 17 and 8 inventions, respectively, in various stages of development with CCF Innovations. The majority of Dr. Lieberman’s projects are related to spinal surgery, including innovative fixation devices and methods and apparatus for correcting scoliosis and stabilizing adjacent bones. Dr. Lieberman’s Merlot Bone Anchor device for endoscopic scoliosis surgery is nearing release after eight years in development.

Dr. Muschler, who holds a joint appointment with the Department of Biomedical Engineering, has specialty interests in fracture nomination and reconstructive surgery, leading to a concomitant interest in tissue engineering. His Cellect Selective Retention Technology uses minimally invasive bone marrow harvesting to populate graft material, with a three- to fourfold increase in progenitor cell concentrations. It has been licensed to Johnson & Johnson since 2004 and is commercially available. Continuing his interest in this area, Dr. Muschler’s current inventions also are related to bone marrow harvesting, bone grafting and limb lengthening.

Other Cleveland Clinic orthopaedic surgeons and their inventions in progress with CCF Innovations include Viktor Krebs, M.D., and Waid Barsoum, M.D., expanding material fastening system; Kenneth Marks, M.D., acellular cup, in partnership with Dr. Lieberman; Peter Evans, M.D., Ph.D., carpal tunnel guide; Robert Biscup, D.O., bone processing device; and Robert McLain, M.D., cunulated ultrasound device for pedicle screw placement.

Chris Coburn is Executive Director of CCF Innovations. He can be reached at 216/445-4008 or at coburnc@ccf.org.

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Numerous surgical options for addressing displaced distal radius fractures exist, including internal and external fixation. While volar plating for certain types of distal radius fractures has been used in the past, dorsally placed plates and cortical fixators have dominated. Recently, newer constructs that provide a locked volar plate have expanded the indications for placing distal radius fractures. Today, volar locked plates are being used in a majority of distal radius fracture types. Although many of these fractures exhibit dorsal displacement and dorsal comminution, which are better biomechanically addressed with a dorsal plate in buttress mode, enthusiasm for routine dorsal plating of distal radius fractures has been limited by complications associated with extensor tendons. Extensor tendon adhesions, tendonitis, and tendon ruptures are thought to occur because of the limited soft tissue interposed between the dorsally applied plates and the extensor tendons. With the ability to lock the screws at various angles, a blade plate-type rigid construct is created. Therefore, despite being placed on the volar side of a dorsally displaced fracture, the articular surface and subchondral bone can be maintained in a reduced position during healing. Depending on the system, the angle that the distal fixed screws/pegs make with the plate allows various fracture fragments to be addressed individually. Perceived concerns with the volar approach include injury to the radial artery and/or median nerve. A modified Henry approach with incision of the flexor carpi radialis (FCR) sheath allows a reproducible exposure with protection of the neurovascular structures. The surgeon makes a longitudinal incision overlying the FCR tendon. The FCR tendon is then retracted radially, and the surgeon incises the floor of the FCR sheath. Blunt dissection allows identification of the pronator quadratus, which is then incised off the radial aspect of the radius, leaving a cuff of tissue for later repair. This approach exposes both the fracture site and the area for the volarly placed plate. To allow for further mobilization, or in the subcutaneous setting, the brachioradialis can be subperiosteally elevated and released, thus eliminating its deforming force upon the distal fragment. The fracture is then reduced and provisionally stabilized with a styloid K-wire or, alternatively, with the aid of the plate and the provisional K-wire holes provided in some systems. Following final plate placement, bone grafting through a small incision dorsally can be made to fill the void left by the implanted cancellous bone. Based upon stability, a typical postoperative course involves seven to 10 days in a postoperative splint, followed by a thermal plastic splint. An early supervised protocol of wrist and forearm range of motion as well as maintained digital and shoulder motion and edema control also are recommended. At approximately eight to 10 weeks, based upon clinical and radiographic progress, one may begin progressive strengthening.

**In Step with Diabetic Foot Care**

Simple wounds in the diabetic foot can rapidly progress from minor problems to limb-threatening ulcers due to the presence of diabetic vascular disorders and neuropathy. The Cleveland Clinic Diabetic Foot Care Program, established in 2003, applies the latest treatments, technology and computer approaches to prevent and manage wounds and ulcers in the diabetic foot. People with diabetes have a lifetime risk of 15 percent of developing a foot ulcer, as non-healing ulcer is the most common antecedent to lower-limb amputation. Our aggressive team approach includes ulcer prevention and treatment, regular foot examinations, patient education, and therapeutic intervention to reduce the risk of ulcers and lower-extremity amputations. Patients with emergent problems are scheduled for immediate consultation in our Diabetic Foot Care Clinic within the Department of Orthopaedic Surgery so that appropriate treatment and intervention can be initiated promptly. Other patients receive a comprehensive evaluation that includes foot pressure mapping together with vascular and neurologic workups to identify risk factors and to define the cause of ulcers and other problems. Physicians apply the PEDIS (perfusion, extent/size, depth/tissue loss, infection and sensation) classification system to assess ulcers and evaluate progress toward healing so that staging and description of ulcers is consistent. To complement this standardization, our electronic medical records system has been enhanced to capture photographs of wounds as part of the patient’s medical record. This innovation allows clinicians to track wound healing more effectively and consistently. Relief of weight bearing is critical in the healing of diabetic foot ulcers and is well documented in the literature. Yet it is frequently overlooked or undertreated by many clinicians and, therefore, remains the single most significant reason that ulcers in the diabetic foot fail to heal. Our clinicians often use a total contact cast, which encloses the foot, as an integral part of the treatment plan. This device effectively relieves pressure to allow the ulcer to heal. With a total contact cast, changed regularly and closely followed by the physician, ulcers heal in an average of 42 days, compared with healing times as long as a year with treatments that do not address the weight relief issue. We have achieved similar rapid healing times in ulcers that have remained open for as long as two years. After an ulcer is healed, managing the foot’s mechanical interaction with the world is critical to preventing ulcer recurrence, which, in various studies, has been shown to occur in 50 percent to 100 percent of patients within three years. Proper footwear can reduce this risk significantly. Our research team uses computer modeling based on MRI images to digitally reconstruct feet in three dimensions (see accompanying article on p. 12). This will eventually enable individualized footwear recommendations to be made for each patient.

**Volar Plating of Distal Radius Fractures**

By Jeffrey N. Lawton, M.D., and Peter J. Evans, M.D., Ph.D., FRSCC

Today, volar locked plates are being used in a majority of distal radius fracture types. Although many of these fractures exhibit dorsal displacement and dorsal comminution, which are better biomechanically addressed with a dorsal plate in buttress mode, enthusiasm for routine dorsal plating of distal radius fractures has been limited by complications associated with extensor tendons. Extensor tendon adhesions, tendonitis, and tendon ruptures are thought to occur because of the limited soft tissue interposed between the dorsally applied plates and the extensor tendons. With the ability to lock the screws at various angles, a blade plate-type rigid construct is created. Therefore, despite being placed on the volar side of a dorsally displaced fracture, the articular surface and subchondral bone can be maintained in a reduced position during healing. Depending on the system, the angle that the distal fixed screws/pegs make with the plate allows various fracture fragments to be addressed individually. Perceived concerns with the volar approach include injury to the radial artery and/or median nerve. A modified Henry approach with incision of the flexor carpi radialis (FCR) sheath allows a reproducible exposure with protection of the neurovascular structures. The surgeon makes a longitudinal incision overlying the FCR tendon. The FCR tendon is then retracted radially, and the surgeon incises the floor of the FCR sheath. Blunt dissection allows identification of the pronator quadratus, which is then incised off the radial aspect of the radius, leaving a cuff of tissue for later repair. This approach exposes both the fracture site and the area for the volarly placed plate. To allow for further mobilization, or in the subcutaneous setting, the brachioradialis can be subperiosteally elevated and released, thus eliminating its deforming force upon the distal fragment. The fracture is then reduced and provisionally stabilized with a styloid K-wire or, alternatively, with the aid of the plate and the provisional K-wire holes provided in some systems. Following final plate placement, bone grafting through a small incision dorsally can be made to fill the void left by the implanted cancellous bone. Based upon stability, a typical postoperative course involves seven to 10 days in a postoperative splint, followed by a thermal plastic splint. An early supervised protocol of wrist and forearm range of motion as well as maintained digital and shoulder motion and edema control also are recommended. At approximately eight to 10 weeks, based upon clinical and radiographic progress, one may begin progressive strengthening.

**In Step with Diabetic Foot Care**

By Peter Cavanagh, Ph.D., D.Sc., and Georgeanne Botek, D.P.M

Simple wounds in the diabetic foot can rapidly progress from minor problems to limb-threatening ulcers due to the presence of diabetic vascular disorders and neuropathy. The Cleveland Clinic Diabetic Foot Care Program, established in 2003, applies the latest treatments, technology and computer approaches to prevent and manage wounds and ulcers in the diabetic foot. People with diabetes have a lifetime risk of 15 percent of developing a foot ulcer, as non-healing ulcer is the most common antecedent to lower-limb amputation. Our aggressive team approach includes ulcer prevention and treatment, regular foot examinations, patient education, and therapeutic intervention to reduce the risk of ulcers and lower-extremity amputations. Patients with emergent problems are scheduled for immediate consultation in our Diabetic Foot Care Clinic within the Department of Orthopaedic Surgery so that appropriate treatment and intervention can be initiated promptly. Other patients receive a comprehensive evaluation that includes foot pressure mapping together with vascular and neurologic workups to identify risk factors and to define the cause of ulcers and other problems. Physicians apply the PEDIS (perfusion, extent/size, depth/tissue loss, infection and sensation) classification system to assess ulcers and evaluate progress toward healing so that staging and description of ulcers is consistent. To complement this standardization, our electronic medical records system has been enhanced to capture photographs of wounds as part of the patient’s medical record. This innovation allows clinicians to track wound healing more effectively and consistently. Relief of weight bearing is critical in the healing of diabetic foot ulcers and is well documented in the literature. Yet it is frequently overlooked or undertreated by many clinicians and, therefore, remains the single most significant reason that ulcers in the diabetic foot fail to heal. Our clinicians often use a total contact cast, which encloses the foot, as an integral part of the treatment plan. This device effectively relieves pressure to allow the ulcer to heal. With a total contact cast, changed regularly and closely followed by the physician, ulcers heal in an average of 42 days, compared with healing times as long as a year with treatments that do not address the weight relief issue. We have achieved similar rapid healing times in ulcers that have remained open for as long as two years. After an ulcer is healed, managing the foot’s mechanical interaction with the world is critical to preventing ulcer recurrence, which, in various studies, has been shown to occur in 50 percent to 100 percent of patients within three years. Proper footwear can reduce this risk significantly. Our research team uses computer modeling based on MRI images to digitally reconstruct feet in three dimensions (see accompanying article on p. 12). This will eventually enable individualized footwear recommendations to be made for each patient.
Artificial Discs: Long-awaited Alternative to Lumbar Fusion

Lumbar fusion continues to be one of the most prevalent spinal surgeries in the United States, yet data reveal that not all of those with degenerative disc disease who undergo the surgery will experience significant pain relief and functional restoration. Total disc replacement with an artificial disc is considered the most promising alternative to spinal fusion, and orthopaedic surgeons have worked for 20 years to develop a successful prosthesi. Until recently, the ideal artificial disc has eluded developers. Now, the latest generation of these prostheses draws on advances in technology, materials and biomechanics, allowing the prostheses to closely imitate the function of the native disc. Cleveland Clinic spine surgeons are involved in the development, testing and early adoption of two of the most promising new disc replacements.

Freedom Lumbar Disc

By Isador Lieberman, M.D.

The Freedom Lumbar Disc (AxioMed Spine Corp., Beachwood, Ohio) is an innovative new artificial disc comprising a polymeric gel core bonded to titanium retaining plates. The polymer’s material characteristics, in combination with the implant design, provide 3-D motion, load sharing, shock absorption and dynamic stiffness as needed in response to varying loads in a fashion that replicates the function of a normal, healthy disc.

European trials of the Freedom disc are scheduled to begin in the fall of 2005, and U.S. trials are scheduled to begin six months later. The prosthesis is designed for patients 30 to 50 years old with early- to mid-stage degenerative disc changes and mechanical back pain who have not responded to nonoperative treatment.

We are not yet sure of precisely what the disc’s role will be in the treatment of symptomatic degenerative discs. The decision of when to use it will depend on a balance of patient expectations, the appropriate timing for surgery and the results that realistically can be achieved. We do know that the Freedom disc is not suitable for patients with end-stage degenerative discs; these patients still will require fusion.

Under laboratory conditions’ worst-case scenario – simulating a person jumping 1,000 times a day and landing on his heels – the Freedom disc had a service life of 40 years.

The Charite Artificial Disc

By Robert McLain, M.D.

The Cleveland Clinic is among the first institutions in the United States to use the Charite artificial disc (DuPuy Spine, Raynham, Mass.) in clinical practice. Approved by the U.S. FDA in October 2004, the Charite disc is a metal/polyethylene insert that restores alignment and allows controlled motion in the spine.

The ideal patient is 30 to 50 years old, with good bone quality and no significant nerve compression. Although the FDA has set age 65 as the upper limit, bone quality and degeneration are the determining factors in patient selection, and the disc will find its best applications in younger patients.

The Charite disc offers significant advantages over lumbar fusion in that it maintains spinal flexibility and reduces the risk of repeat fusions, but that does not change the fact that patient selection is paramount. If a patient is not a fusion candidate, the Charite artificial disc is not an appropriate treatment.

DuPuy Spine has designated The Cleveland Clinic as a training center for teaching orthopaedic spine surgeons the implantation technique for the Charite disc. The procedure is best reserved for spine surgeons experienced in an anterior approach to vertebral surgery because of the complexities involved. In some cases, a vascular surgeon may assist in the exposure of the anterior vertebral body and disc space.

When the vessels and organs have been displaced and the vertebrae is in view, the spine surgeon excises the degenerated disc. The Charite artificial disc is press-fit into position, where it is held in place by the natural vertebral tension. In the hands of an experienced surgeon, operative time is shorter than for a lumbar fusion and blood loss is minimal.

Most patients require a two- to four-day hospital stay and are ambulatory postoperatively without a brace. Following surgical healing and rehabilitation to regain strength and balance, activity is virtually unrestricted.

Bone Mineral Density (BMD) in Women: Effects of Exercise

By Susan Joy, M.D.

Exercise across the lifespan is a key component of bone health. Adult premenopausal exercisers demonstrate increased lean mass compared with sedentary controls, and those exercising with higher impact have greater leg strength and higher whole-body and regional bone mineral density (BMD). Eumenorrheic athletes in the highest impact and jumping sports have the highest BMD in weight-bearing areas and demonstrate the highest levels of bone formation markers.

A positive association exists between BMD and resistance (e.g., strength, weight) training. Novel strength training introduced to postmenopausal women positively affects BMD, and the effect at specific sites correlates with the cumulative amount of weight lifted.

Although highly trained and elite female athletes demonstrate increased BMD in loaded regions, the effect of high levels of activity on bone can be detrimental. The literature consistently supports the contention that the osteogenic effects of exercise are modulated in a complex manner by the nutritional and hormonal status of the athlete. For example, female elite-level winter sports athletes with normal menstrual function have higher BMD compared with age- and body mass-matched controls, a difference that remains significant after controlling for lean mass. However, those athletes with a history of oligo- or amenorrhea seem to lose the osteogenic benefit of their sport participation and demonstrate similar BMD as eumenorrheic, nonathletic controls.

Dancers and gymnasts exhibit this same effect. Amenorrheic dancers more often report delayed menarche and a higher incidence of dietary behaviors than eumenorrheic dancers. They also demonstrate significantly lower BMD over time and may have an increased risk of stress fractures. Collegiate female gymnasts have higher BMD at all sites prior to and during the competitive season than runners, despite a greater reported prevalence of menstrual dysfunction. Because of the tremendous repetitive loads applied to various skeletal sites in the sport of gymnastics, dramatic responses in bone formation can be observed at multiple sites associated with greater size-adjusted strength measures.

The Female Athlete Triad

When energy intake does not keep up with the demands imposed upon the body by strenuous exercise, an energy deficit can result. Research has suggested that the negative observed effects are not from the exercise itself but rather from the energy imbalance created in this scenario. Whether or not caloric restriction is intentional, a relative energy deficit in relation to demand is understood to be the trigger of a biochemical and hormonal cascade that ultimately deleteriously affects bone in the setting of the Female Athlete Triad.

The Female Athlete Triad syndrome, as originally defined, results from disordered eating, which in turn causes hypothalamic amenorrhea and subsequent osteopenia in athletic women. It is now understood to represent more of a continuum involving energy balance, menstrual dysfunction and bone mineralization. All athletic women should be routinely screened for such behaviors, risk factors or possible sequelae of the Triad. The effects of exercise on female bone health are likely modulated by a number of complex factors including genetics, age, lifetime history of activity, current history of activity, diet and nutritional status, and contraceptive use, to name a few. It is important to lend some consideration to all these issues when providing comprehensive care to female athletes of all ages.

Dr. Susan Joy, Director of Women’s Sports Health and a member of the Orthopaedic Surgery Department’s Section of Sports Medicine, can be reached at 216/986-4000 or toll-free at 877/440-TEAM (8326). 

Photo courtesy of DuPuy Spine Inc., of the departments of Orthopaedic Surgery and Neurological Surgery, has been designated by DuPuy Spine as a clinical instructor for the Charite artificial disc. He can be reached at 216/444-2744 or at mclainr@ccf.org.

Dr. Isador Lieberman, of the Departments of Orthopaedic Surgery and Neurological Surgery, is one of the developers of the Freedom Lumbar Disc and will participate in the U.S. trials. He can be reached at 216/444-2743 or at lieberi@ccf.org.

Photo courtesy of DuPuy Spine Inc.
Alternative Bearings in Hip Replacement
By Wael K. Barsoum, M.D., Robert Molloy, M.D., and Viktor Krebs, M.D.

Seniors are the fastest growing subset of the American population. It is estimated that by 2030, 70 million people will be over age 65, up from 35 million in 2000. For the arthritic population, many of whom are seniors, alternatives to improve quality of life are essential. In the absence of a cure, total joint replacement is one of the most successful interventions available to those with arthritis. The prognosis of this disease has significantly improved with hip replacements and advances in prosthetic technology.

A great deal of research, including studies performed at The Cleveland Clinic, has been conducted with an eye toward developing materials with extended wear resistance. In theory, if we can decrease the wear particles generated in a hip replacement, the prosthesis should last longer. In our clinical experience, most patients we see initially believe a hip prosthesis will last 10 to 15 years. However, in the last five years, new technologies have allowed us to utilize materials that change this perception dramatically. In addition, new materials have been introduced that may live up to the promise of extended wear resistance, while more are being developed.

Hip replacements depend on a bearing surface to replace the worn-out portion of the joint. As with any type of bearing, the surfaces in the hip are subject to friction, which, after time, leads to wearing of the bearing surface. The wear particles generated cause an inflammatory reaction by the body’s immune system. In an effort to “wall off” these wear particles, the immune cells actually trigger bone loss; thus, the joint wears out. As new materials become available, hip replacements are offered to patients earlier, allowing them to get back to their lifestyles as soon as possible. Newly developed materials and bearings that show promise of extended wear resistance include highly cross-linked polyethylene, metal-on-metal bearings, and ceramic-on-ceramic bearings. A method of increasing the bonds within a polyethylene bearing, highly cross-linking polyethylene, has been shown to decrease wear by 90 percent in some laboratory studies. An improved metal-on-metal bearing, already showing impressive short-term results, has enjoyed a recent rebirth in the United States.

The most recent FDA-approved material in the United States is ceramic bearing. These bearings have shown up to a 99 percent decrease in the generation of wear particles in the laboratory. It is hoped that ceramic bearings will offer a longer life span for the prosthesis and decrease revision rates.

In terms of wear resistance, ultimately time is the test. While we follow our patients and track the results of new bearings, we are constantly looking to advance to newer technologies so that we may offer patients hip replacements that last a lifetime.

As of this writing, a new bearing is being developed that will actually use a synthetic diamond. Imagine that!

Dr. Victor Krebs, Head of the Section of Adult Reconstruction at the Cleveland Clinic’s main campus, specializes in total joint replacement, revision total joint replacement and hip and knee arthroscopy. He can be reached at 216/445-3834 or 800/553-5056, ext. 53854.

Dr. Wael K. Barsoum, a member of the Section of Adult Reconstruction, specializes in arthroscopy, reconstruction and replacement of hip, knee and shoulder joints at Cleveland Clinic Westlake. He can be reached at 440/908-4882.

Cleveland Clinic Scientist Wins Academy Award

Antoine (“Tony”) van den Bogert, Ph.D., of the Cleveland Clinic Department of Biomedical Engineering, was presented with an Academy Award from the Academy of Motion Picture Arts and Sciences in Los Angeles earlier this year. The award specifically was for Technical Achievement, honoring Dr. van den Bogert and three colleagues from outside the Clinic for their work with motion capture software.

Motion capture technology uses special cameras that track the motion of reflective markers attached to the human body and convert this motion into animation using data captured from the camera. Once the captured data are stored in the computer, can be processed, analyzed or used to create animation.

Motion capture technology has been used since the mid-1980s as a research tool to study the biomechanics of human movement, but, until recently, the technology often produced results that did not have the quality required for movies and computer games.

“Often one could see feet sliding on the floor or bones changing length,” says Dr. van den Bogert. This prompted him to invent a new algorithm, based on mathematical models of the human skeleton, to refine and smooth the motions, making the animation look more like real human movement.

In the biomechanics laboratory in the Department of Biomedical Engineering at the Cleveland Clinic Lerner Research Institute, Dr. van den Bogert applied his new algorithms to allow a much more accurate analysis of skeletal motion during sport movements than was previously possible. For example, a recent study on knee ligament injuries involved recording the movements of a group of elite-level basketball players and recreational athletes using high-speed motion analysis equipment – six cameras track motion at a speed of 240 frames per second. Dr. van den Bogert then generated random “mistakes” in their movements to simulate injuries and identify the attributes that contributed to the ACL injuries.

In addition to biomechanical applications, Dr. van den Bogert’s motion capture software has been used to produce computer games such as “NBA Live 2004” and “Tiger Woods PGA Tour 2004,” as well as in major motion pictures such as Lord of the Rings, I, Robot, the remake of King Kong, The Matrix Reloaded, and The Matrix Revolutions.

Dr. Ton van den Bogert, of the Department of Biomedical Engineering and the Orthopaedic Research Center, is interested in the areas of biomechanics, joint injury and motor control. He can be reached at 216/444-5566.

Using ECMs as Regenerative Scaffolds for Tendon Repair
By Kathleen Derwin, Ph.D., and Joseph P. Iannotti, M.D., Ph.D.

In recent years, natural extracellular matrices (ECMs) have been marketed for clinical use as patches to reinforce soft tissue repair, several with a specific indication for rotator cuff surgery. The ECMs are derived from dermis (GraftJacket, Permacol, OrthoMend) and small intestine submucosa, or SID (Restore, CellPatch). Limited peer-reviewed literature exists on the efficacy of these products for tendon repair or augmentation, and no retrospective or prospective clinical trials have been published using these materials for tendon applications. Consequently, Cleveland Clinic orthopaedic physicians and researchers have been evaluating these commercial products for tendon repair. Our work has demonstrated that these ECMs are significantly more compliant than tendon, especially at physiologic strains for tendon (~5%), suggesting that these ECMs should be stretched at implantation in order to realize their mechanical potential. The primary advantage of these commercial ECMs, however, may be more biologic than mechanical.

Auto- and allograft fascia lata have been used clinically for tendon repair for several decades; however, the concept of optimizing human fascia lata as a more standardized, allowed us to utilize materials that may change repair has not been developed. Fascia lata ECM has similar composition to tendon.

At The Cleveland Clinic, we are developing human fascia lata as a regenerative scaffold for musculoskeletal soft tissue repair. We envision a fascia product that will offer both sufficient mechanical strength as well as an appropriate milieu to “kick-start” the wound-healing process. Fascia ECM may provide an attractive alternative to using a dermis or SID-derived ECM for tendon repair.

Dr. Joseph Iannotti, Chairman of the Department of Orthopaedic Surgery, is Co-Chairman of the Orthopaedic Research Center and a member of the Section of Hand and Upper Extremity Surgery. He can be reached at 216/445-5151.

Dr. Kathleen Derwin, a member of the departments of Biomedical Engineering and Orthopaedic Surgery, is interested in tendinology and tissue engineering. She can be reached at 216/445-5982.
Total Shoulder Replacement: Improving Outcomes with Proper Prosthetic Selection
By Joseph P. Iannotti, M.D., Ph.D.

In 2004, upper extremity surgeons within the Cleveland Clinic’s Department of Orthopaedic Surgery performed nearly 300 shoulder replacements for a wide variety of shoulder arthritic and traumatic disorders. The ability to obtain optimal results is a combination of surgical technique, prosthetic design and postoperative rehabilitation. Charles S. Neer II, M.D., developed the first modern shoulder prosthesis 40 years ago. In the 1980s, shoulder replacement was demonstrated to be durable and effective for many types of arthritis but was most effective for the treatment of the older, more sedentary patient with advanced osteoarthritis with an intact rotator cuff. Technical and disease-related challenges remained when treating young, active patients that had higher functional demands and longer life expectations. In these cases, there was justifiable concern for premature implant failure. In the late 1990s, shoulder prosthetics that were more bone sparing were developed and helped to improve clinical failures related to the high loads associated with the young, active patient.

In patients with severe rotator cuff damage, the standard prosthetics that proved to be so effective for treatment of arthritis with an intact rotator cuff demonstrated more variable and less predictable functional results. Other prosthetics were designed for the patient with severe loss of function associated with severe arthritis and massive irreparable rotator cuff tears.

Currently, the type of shoulder prosthesis used is tailored to the type of shoulder arthritis as well as to the patient’s age and anticipated activity level. Thus, patients have greater options for long-term function and for optimizing the results of surgery.

A standard shoulder prosthesis (Figure 1) has a stemmed humeral component that is fitted or cemented into the humeral shaft. Third-generation stemmed humeral implants have a modular humeral head component that is sized to the patient’s normal anatomy and is adjustable to compensate for variations in humeral head position with respect to the anatomic axis of the stem. The glenoid and humeral components are unconstrained, and the function of the shoulder is dependent upon the function of the rotator cuff.

The polyethylene component is commonly fixed with a set of pegs (Figure 2). The Anchor Peg glenoid component currently used at The Cleveland Clinic has very low incidence of glenoid loosening, but concern remains for wear debris resulting in particulate-generated component loosening. Glenoid wear is a greater concern with the younger and active patient due to the patient’s activity level and life expectancy.

The young and active patient has high functional demands and a long life expectancy, making any prosthetic failure likely to fail over the life of the patient. In these circumstances, a more conservative humeral replacement uses a reaming tool to reshape the articular head and place the resurfacing non-stemmed humeral component (Figure 3). Without humeral head resection, access to the glenoid is limited, and a polyethylene component is not easily placed, nor is it desirable in the younger active patient.

In cases when glenoid resurfacing is required, an autogenous soft tissue glenoplasty is obtained from the resected joint capsule or from allograft tissue, most commonly taken from the Achilles tendon or knee lateral meniscus. Suture anchors are placed circumferentially around the glenoid at its rim, and the soft tissue is secured to the glenoid (Figure 4). It is anticipated that the soft tissue will improve the functional result over hemiarthroplasty alone and will prevent the issues associated with wear and loosening of the polyethylene component. This bone-conservative approach used in the first replacement will allow for a standard replacement to be used in a way that is similar to that which would be seen with a first-time surgery.

In an older patient with a massive irreparable rotator cuff tear, standard non-constrained humeral hemiarthroplasty is likely to yield a poor functional result because the containment and centering function of the rotator cuff is lost, and the deltoid is incapable of elevating the arm without this centering function. In this clinical scenario, a non-designed constrained reverse total shoulder arthroplasty can substitute for the function of the absent rotator cuff and allow the deltoid to elevate the arm above shoulder level. In the design used at The Cleveland Clinic, the center or rotation is moved medially to the interface between the glenoid and prosthetic thereby markedly decreasing the stress and likelihood of glenoid component loosening. This also improves the strength of the deltoid by increasing its moment arm (Figure 5).

The European experience with this prosthetic over the last 10 years has demonstrated excellent clinical results. This prosthetic was first FDA approved in the United States in March 2004. Since that time, Cleveland Clinic shoulder surgeons have implanted over 60 reverse implants, 40 of which have been in cases with other failed prosthetic implants. Our early results correlate well with the excellent clinical results seen by the European surgeons (Figure 6).

Current clinical practice now allows for selection of a prosthetic design that is best suited for the patient’s pathology, age and anticipated activity level. Although not all patients and pathologies are a best fit for these three prosthetic designs, they nonetheless allow best options for the improvement of function and joint stability for the prosthetic, and thereby for many patients.

Dr. Joseph Iannotti, Chairman of the Department of Orthopaedic Surgery, and Staff, Section of Upper Extremity Surgery, can be reached at 216-4445-5151.
Residual hip dysplasia remains a significant cause of degenerative joint disease in the adult hip. Relatively minor alterations in hip mechanics due to a shallow, dysplastic acetabulum produce increased shear forces, joint loading and, ultimately, rapid degeneration of the native hip joint. While recent advances in materials technology and surgical techniques can theoretically prolong the life of a total hip prosthesis, no substitute for the native hip joint exists; thus, prolonging its survival remains paramount. Correction of mechanical abnormalities due to residual dysplasia during the childhood and adolescent years has been shown to reduce symptoms and prolong the life of the native hip joint. Residual dysplasia in the adolescent years typically presents with symptoms such as a limp or Trendelenburg gait, groin pain or other subtle functional limitations. Some patients may only report difficulty with sports or other aggressive activities. Others may be asymptomatic. Positive findings on physical exam include mild asymmetry in hip motion, positive Trendelenburg gait or sign, or pain with hip range of motion. Sometimes no abnormalities are found. Plain radiographs are typically sufficient to make the diagnosis of acetabular dysplasia. 3-D CT scans are valuable in defining the extent and location of dysplasia and are critical in preoperative planning. Evidence of degenerative joint disease or incongruence of the hip joint should be noted if present. Closure of the triradiate cartilage varies with patient age and gender and should also be noted. Surgical treatment is indicated in select patients with residual acetabular dysplasia that produces symptoms or in those with concomitant subluxation. The goals of surgery include relief of the patient’s symptoms, normalization of acetabular anatomy and prolonging the life of the native hip joint. Redirectional pelvic osteotomies are typically the main surgical option for achieving these goals. Evidence of degenerative joint disease or incongruence of the hip joint remains critical intraoperatively before the procedure. The TIO involves three cuts in the pelvic one in the ilium, one in the pubis and one in the ischium. Internal fixation is typically applied to the iliac and pubic osteotomies, after which pa- tients can be mobilized without a spica cast, provided the fixation is satisfac- tory. The procedure typically requires two incisions, and direct visualization of the osteotomies is possible. The PAO is accomplished through a single larger incision and involves more precise juxta-acetabular cuts. Specialized osteotomies are used and image intensifi- cation is critical intraoperatively be- cause some of the cuts are not directly visualized in the surgical field. The PAO should not be considered if the triradiate cartilage remains open. Aftercare involves protected weight bearing and gentle mobilization until radiographic union is present. Most ado- lescents do not require implant removal unless they become symptomatic. In most cases, patients can resume full activities, including sports. The major difference be- tween the PAO and the TIO is that the posterior column is left intact with a PAO and earlier weight bearing can be permit- ted. Again, the PAO is contraindicated in pa- tients with an open triradiate cartilage, making the TIO an excellent choice in these patients. The learning curve for both procedures is significant; thus, surgeons should obtain special training, including observation and cadaver work, before using these procedures extensively in any given practice. Residual acetabular dys- plasia continues to pose a unique clinical problem in adolescent patients. While it remains contro- versial as to whether or not patients with residual dysplasia should be of- fered surgery in the ab- sence of symptoms, it seems clear that in symp- tomatic patients, joint preserving procedures such as the TIO and PAO are effective in correcting abnormalities of hip biomechanics and, ultimately, prolonging the life of the native hip.

Dr. Ryan Goodwin is a member of the Section of Pediatric Orthopaedic Surgery, specializing in hip disorders, scoliosis and trauma. He can be reached at 216/445-4024.

Orthopaedic Surgery Residency Update
By Thomas Kuivila, M.D.

The Cleveland Clinic Orthopaedic Surgery Residency Program continues to thrive and produce orthopaedic surgeons ready to lead the specialty into the 21st century. Our de- partrtment’s educational mission is to educate residents who will provide outstanding pa- tient care, lead the orthopaedic community of the future and contribute to the orthopaedic fund of knowledge through clinical and basic science research.

- We are currently in the process of applying to the ACGME for an increase in our resi- dent class size. Our department has had four residents per year since the 1970s, and yet our clinical productivity has grown several-fold and the orthopaedic surgery staff has nearly quintupled. The goal is to increase our resident class to six residents per year. This will not only afford the residents greater educational opportunities at the main campus, but it also will allow greater participation by residents in the growing educa- tional and clinical activities at Lutheran Hospital, a community hospital within the Cleveland Clinic Health System.
- Alumni Director, Blaine McCoy, M.D., hosted an outstanding alumni program at the inau- gural Orthopaedic Alumni Day held at the Cleveland Clinic main campus in September 2004. There was excellent participation by orthopaedic surgery alumni from around the country, and we look forward to our next non-AAOS alumni gathering with anticipation.
- A warm welcome from the Department of Orthopaedic Surgery is extended to the in- coming class of Orthopaedic Surgery interns. Those selected for the incoming class be- ginning July 1, 2005, are: John Ryan, 2005 graduate of Case Western Reserve University School of Medicine; John Bottros, 2005 graduate of the State University of New York at Syracuse College of Medicine; Ryan Patterson, 2005 graduate of the Uni- versity of California-Irvine College of Medicine; and Carlos Higuera, 1999 graduate of Pontificia Universidad Javeriana in Bogota, Columbia. Dr. Higuera is currently a General Surgery intern at The Cleveland Clinic. We are exceptionally pleased with our entering class of 2005. These gentlemen represent the cream of our applicant crop. We received in excess of 400 applications and interviewed 48 outstanding individuals. The four selectees were in our top-10 ranked applicants.
- Five years ago the residency expanded from a five-year program to a six-year program. The residents who graduated this year mark the last group of five-year orthopaedic surgery residents. We bid a fond adieu to this year’s graduates:

- Richard Dal Canto, M.D., Ph.D., a Northwestern University alumnus and a 2000 graduate of the University College of Medicine who will be a fellow in pediatric orthopaedic surgery at Texas Scottish Rite Hospital in Dallas next year.

- David Gurd, M.D., a Miami University graduate and a 2000 graduate of the Ohio State University College of Medicine who will be a fellow in pediatric orthopaedic surgery at Texas Scottish Rite Hospital in Dallas next year.

- Richard Dal Canto, M.D., Ph.D., a Northwestern University alumnus and a 2000 gradu- ate of Stanford University School of Medicine, has accepted a position as a fellow in orthopaedic surgery in the ab- sence of symptoms, it seems clear that in symp- tomatic patients, joint preserving procedures such as the TIO and PAO are effective in correcting abnormalities of hip biomechanics and, ultimately, prolonging the life of the native hip.

- Dr. Ryan Goodwin is a member of the Section of Pediatric Orthopaedic Surgery, specializing in hip disorders, scoliosis and trauma. He can be reached at 216/445-4024.
Shoulder Arthrosis in the Young Patient: Treatment Options
By Anthony Miniaci, M.D.

Osteoarthritis of the shoulder is being recognized more frequently as a condition for which treatment can offer significant improvement in pain relief and function. A better understanding of shoulder anatomy and function as well as improvements in implant design have resulted in more treatment options for patients with arthritic shoulders. Across the world, shoulder surgery in general and shoulder arthroplasty surgery specifically, are two of the most rapidly expanding areas in orthopaedic surgery.

Patients younger than 50 can have significant disability with arthritic shoulders, and few options have existed for them. Many can get arthritis as a result of trauma or repetitive stress from heavy lifting, or following stiffness as a result of surgery or injury. Many treatments, including various arthroscopic techniques and cartilage resurfacing procedures, have been described for treating arthritis in young patients. Various biological resurfacings of the joint have been attempted in the shoulder of younger patients with some success. Recently, some newer implant designs and concepts have allowed us to combine biological glenoid resurfacing with metal partial or full-surface replacements that are less disruptive to the patient’s own anatomy and leave options for the future.

Surgical Options

Arthroscopic Lavage, Debridement, and Microfracture
Capsule Releases

Joint debridement, lavage and drilling were described as early as 1941 for the knee joint. The rationale of treatment was to remove loose debris and mechanical obstruction from the joint. Although patients experience early relief of symptoms, long-term benefits were not sustained and no repair of the defects occurred.

Procedures such as abrasion and microfracture were developed to try to stimulate a healing response via a vascular repair by perforating the subchondral bone. These procedures result in a fibrocartilage repair that gives good early clinical results but is less promising in the long term, likely because the biomechanical properties of the fibrocartilage repair are inferior to those of normal articular cartilage.

Patients that develop arthritic problems in the shoulder usually get tightening of their ligamentous structures (the capsule). By releasing these tight ligaments, patients can get some short-term relief of their symptoms. This release results in less compression in the joint and may slow down the progression of arthritis and give some symptom relief. Therefore, any arthroscopic “cleanout” should be combined with release of the capsule in an arthritic knee.

Osteochondral Autograft and Allograft Transplantation

Restoration of the joint surface with osteochondral grafts is the only procedure that actually replaces the defect with intact hyaline cartilage, although the areas between the grafts are filled with fibrous tissue. The entire repaired defect is not hyaline cartilage. In reality, it is islands of hyaline cartilage surrounded by fibrous tissue. Joint surfaces and contours can be restored; however, the size of defects is a limiting factor because only a limited number of autografts are available.

For larger defects, allografts are an option, although tissue viability and cell survival are not as consistent as with autogenous material.

The procedure is technically demanding and requires significant practice at delivering plugs in the appropriate position. In addition, this procedure is not advocated when the joint is arthritic; it is more often used when the defects are isolated. This procedure has been more commonly used in the knee. Results in the shoulder, although sparse, have not been as good.

Interposition Arthroplasty

The concept of interpositional arthroplasty is one where a “Biological Buffer” is placed between the joint surfaces so the arthritic surfaces do not abut, thereby, theoretically, reducing pain. Different graft materials, such as fascia lata or meniscus, have been used to create this interposition with some variable results. When performing these procedures, it is necessary to debride the joint, release the capsule and restore soft tissue balance.

Focal or Complete Joint Prosthetic Resurfacing

Recently, joint resurfacing implants have been developed for younger patients. By resurfacing the joint, bone is preserved. The goal of this procedure is to provide pain relief by restoring a smooth and continuous load-bearing surface. Various implants have been designed to achieve this goal. Some early designs were made spherical. Although the humeral head is big and large spherical in its central portion, it becomes more oval at its edges.

The HemiCAP is a new prosthetic implant designed to resurface the joint. The implant has the ability to better match the patient’s anatomy with its asymmetric options for implantation. The procedure is minimally invasive, offers reduced morbidity, and involves little bone resection, so future total joint procedures aren’t compromised.

The technology allows for the mapping of the articular surface based on a titanium screw inserted into the base of the defect. With accurate measurements, one can then select the size, shape and contour of the implant necessary to reconstruct the defect. The procedure is amenable to an arthroscopic-assisted approach to joint resurfacing with the advantages of lower morbidity and fewer complications.

Animal studies have demonstrated no adverse effects on the opposite articulating surface and no loosening or disruption of the implant. Clinical trials involving the shoulder are progressing. Cleveland Clinic Orthopaedic physicians are working on a minimally invasive arthroscopic technique.

Total Joint Resurfacing with Bone Preserving Techniques

With excellent results thus far, we have combined interpositional arthroplasty with joint resurfacing. The procedure involves using a meniscus allograft on the glenoid side and a HemiCAP on the humerus surface. Our preliminary results have been quite encouraging. Patients have had significant pain relief and more improvement in function than with conventional shoulder arthroplasties. Many patients have demonstrated restoration of full range of motion, even when the arthritic changes were quite severe.

The reasons for these excellent results are not fully delineated. However, they likely involve the ability to maintain the patient’s own anatomy and to restore the humeral surface with a design that more closely resembles the surface being replaced, due to the availability of aseptical and spherical shapes. Another reason may be the placement of a smooth articulating surface against the biological graft.

We are performing these procedures on an open basis but have minimized muscle damage and bone resection during exposure. Most patients require less than a 24-hour hospital stay, and recovery is faster than with conventional shoulder replacements.

Dr. Anthony Miniaci, Department of Orthopaedic Surgery and Executive Director, Cleveland Clinic Sports Health, specializes in management of sports injuries, shoulder and knee reconstruction and cartilage resurfacing. He can be reached at 216/444-2625 or 800/553-5056, extension 42625.

The Cleveland Clinic Orthopaedic CME Calendar

Physicians are welcome to attend the following upcoming clinical and basic science symposia:

A Knee Summit from Cradle to Rocker: An International Exchange of Solutions for Contemporary Knee Problems
Sept. 14-17, 2005
InterContinental Hotel & MBNA Conference Center
Cleveland, OH

Diabetic Lower Extremity Summit: An International Summit on Research and Treatment
Oct. 20-22, 2005
InterContinental Hotel & MBNA Conference Center
Cleveland, OH

3rd Medical Innovation Summit: Orthopaedics Medical Innovations
Oct. 24-26, 2005
InterContinental Hotel & MBNA Conference Center
Cleveland, OH
Visit: clevelandclinic.org/innovations

Cleveland Clinic Bone Summit 2006
May 4-6, 2006
InterContinental Hotel & MBNA Conference Center
Cleveland, OH
Bioabsorbable Interference Screw Fixation of Tendons in Foot & Ankle Surgery

By James J. Sferra, M.D., and Brian G. Donley, M.D.

When performing reconstructive surgery in the foot and ankle, one often has to perform tendon transfers for various reasons. Traditional tendon transfer techniques have been well established, but there can be associated graft length limitations as well as extensive surgical approaches required to harvest such grafts. In response to these pitfalls, various modes of graft fixation have been utilized. The bioabsorbable interference screw is becoming the fixation technique of choice in foot and ankle surgery. Traditional methods of tendon transfer fixation to bone are multitudinous and have included direct suture of the tendon to the periosteum, suture of the tendon into bone troughs, suture anchors (both metal and bioabsorbable), and passage through bone tunnels. These techniques often require sufficient tendon length, which is not always possible, or a length that demands exposure into “hazardous” areas, which is best to avoid. Attempts to harvest the flexor hallucis longus or flexor digitorum longus tendons in the plantar midfoot serve as an example. Bioabsorbable interference screws allow a shorter length of tendon to be transferred and, thus, avoid the extra length and exposure requirements.

A vast experience with bioabsorbable screws has been gained in anterior cruciate ligament surgery of the knee. The principles that have been established in the knee have recently been applied to tendon transfers in the foot and ankle. Type III collagen fibers (Sharpey’s fibers) interconnect the interface between the tendon and bone six weeks postoperatively. Thus, bone blocks at the end of the transferred tendons are no longer necessary. Also, a recent study has shown that fixation using these interference screws results in initial strengths similar to osseous tunnel techniques. Once one gains surgical acumen with these devices, they can save a considerable amount of intraoperative time.

Common foot and ankle procedures that require the use of tendon grafts include transfer of the FDL into navicular; transfer of the flexor hallucis longus (FHL) into the calcaneus; anterior and posterior tibialis tendon transfers for muscle imbalance in neuromuscular disorders; and lateral ankle ligament reconstructions utilizing free tendon segments.

Flexor Digitorum Longus Transfer for Posterior Tibial Tendon Insufficiency

The most common cause of adult-onset flatfoot is posterior tibial tendon insufficiency. Transfer of the FDL into the navicular, transfer of the flexor hallucis longus (FHL) into the calcaneus; anterior and posterior tibialis tendon transfers for muscle imbalance in neuromuscular disorders; and lateral ankle ligament reconstructions utilizing free tendon segments.

Mechanical testing has shown that fixation strength with the screws for this application is one and a half to three times the requisite strength. Ideal drill hole size for each screw comes in various sizes and are cannulated. Because the FDL diameter averages 5 mm, a slightly larger screw is employed. The tendon is placed into the depth of the hole at the desired tension and held firmly while the interference screw is inserted. The foot is plantar flexed and inverted while the screw is placed. The screw affords a shorter tendon length requirement, less distal dissection into the venous region, a smaller incision, less likelihood of bone fracture and a shorter operative time.

Flexor Hallucis Longus Transfer for Achilles Problems

Several Achilles tendon problems can be addressed by augmenting the Achilles repair with an FHL transfer. Chronic tendinosis, missed ruptures, and extensive insertional calcific tendinitis are a few examples. The FHL transfer is thought to mechanically strengthen the diseased Achilles tendon and possibly provide blood supply to the degenerative segment of that tendon. Harvest of the FHL through a separate medial midfoot incision to allow adequate length for passage through the calcaneal tunnel and then back onto the FHL allows the tendon to be transferred into the calcaneus with either a suture anchor or an interference screw.

Dr. Brian Donley, Vice Chairman of the Department of Orthopaedic Surgery and a member of the Section of Foot and Ankle Surgery, has a strong interest in research and in the treatment of fractures and bunion deformity, reconstruction after foot and ankle trauma, acquired deformities, including flat feet, and arthritis and sports injuries in the foot and ankle. He can be reached at 216/445-2570 or 800/553-5056, ext. 52570.

Dr. James Sferra, Head of the Section of Foot and Ankle Surgery, specializes in all aspects of foot and ankle reconstruction. He can be reached at 216/445-8507 or 800/553-5056, ext. 58507.

In 2004, The Cleveland Clinic established the Center for Advanced Skills Training (CAST) under the leadership of orthopaedic and spine surgeon Isador Lieberman, M.D. The CAST program offers highly focused short-term programs designed to train practicing physicians in new, innovative and effective surgical or therapeutic techniques. The CAST program involves direct teacher-to-participant interaction and hands-on training through one to four weeklong preceptorships. Allowing physicians to exhaust their learning curve under the direct supervision of leaders in the field makes the CAST program unique. Other unique aspects of the CAST program include schedule flexibility and curriculum tailoring. For example, to meet the specific needs of participants who are willing to take time off from their practice to enhance their knowledge and skills, the CAST Advisory Board accepts requests from physicians who are interested in training in a specialized technique. Thus, if a particular technique is not offered in the catalog, interested physicians can make a special request. The Advisory Board will then identify Cleveland Clinic preceptors who are willing to structure programs around their interests.

For more information about the Center for Advanced Skills Training or to view the catalog, visit www.clevelandclinic.org/education/cast. Contact the CAST office at 216/445-5601, or e-mail Nancy Farrow at farrown@ccf.org.

Center for Advanced Skills Training

Because every physician deserves world-class training

The mission of the Center for Advanced Skills Training is to provide practicing physicians nationally and internationally with the opportunity, environment and facilities to learn new or enhance existing procedural and clinical skills. The Cleveland Clinic has a long history of training postgraduate physicians in innovative technology and procedures, and the CAST program opens new avenues for physicians to acquire world-class training.

Step 1

Step 2

Step 3

Images courtesy of Arthrex, Inc.
Unicompartmental Arthroplasty Gaining Favor; Long-Term Success Yet to Be Proven

By Mark Froimson, M.D.

Knee arthritis is one of the most common causes of disability for which patients seek advice from primary care physicians and orthopaedic surgeons. This disease can present with a wide range of severity and can involve different compartments of the joint with various degrees of severity. Global involvement of the knee with arthritic degeneration or destruction is well treated with total knee replacement. Controversy exists regarding the necessity of total knee replacement when damage is restricted to one area or compartment of the knee and the remaining cartilage is uninvolved.

Unicompartmental arthroplasty is a viable and attractive alternative to total knee arthroplasty when the arthritis mainly involves one compartment of the knee, with relative sparing of the remaining joint. In such instances, it is reasonable to propose resurfacing of only the diseased compartment, thus restoring knee alignment and allowing for load sharing between the replaced and original compartments. While intuitively attractive, this procedure has a history of controversy, due to both early reports of inferior survivorship from loosening or disease progression and the high rates of success for total knee arthroplasty. As new evidence emerges, newer techniques and patient demand have driven a resurgence of interest, with convincing evidence of superior short-term benefits of partial knee replacement without significant compromise to survivorship rates.

Proper indications and meticulous surgical technique are predictors of success for any surgical procedure and are particularly essential for partial knee replacement. Pain should be well localized to the compartment exhibiting disease, and often the patient can point to the offending area with one finger. Diffuse or global pain is less likely to respond to replacement of one compartment. The status of the patellofemoral joint has not been consistently correlated with success, but the presence of pain in the lateral or patellofemoral region of the joint proportionately is a predictor of persistent pain postoperatively. Contraindications to this procedure include inflammatory arthritis, severe fixed deformity, previous opposite compartment meniscectomy and tricompartmental arthritis.

Surgical considerations include appropriate implant-to-implant alignment and adequate correction of deformity to allow proper load-sharing to prevent premature failure. Minimally invasive approaches should not compromise visualization or the ability to accomplish either of these essential goals.

Failure of a unicompartmental arthroplasty may occur due to implant wear, loosening or subsidence, or progression of symptomatic arthritis in the lateral or patellar compartments. Malaligned implants lead to increased peak stress in the polyethylene and, consequently, early wear and loosening. Similarly, undercorrection of joint malalignment can lead to increased stress on the implant and early loosening, while overcorrection risks adverse load conditions in the retained compartment that can lead to symptoms of progressive arthritis and early failure. Recommended correction of the varus knee depends on the optimum predictable alignment for the given patient and may range from one to five degrees of postoperative valgus. Patellar impingement against the femoral implant can be symptomatic and lead to revision. Patellar arthritis generally is well tolerated in unicompartmental arthroplasty. In a recent review of our early experience with this procedure, the short-term results of a group of fifty patients (age 40 to 75) undergoing unicompartmental arthroplasty compared favorably with a matched group of patients who had undergone total knee arthroplasty for similar unicompartmental disease. Although follow up was only two to four years, the focus of the comparison was on the early postoperative experience and initial return to function. The patients with unicompartmental arthroplasty fared better in terms of length of stay, need for rehab facility, postoperative tive morphine use, time to achieve 90 degrees of flexion, ability to ambulate without assistive device and final achieved range of motion (see table).

In addition, although revision of a unicompartmental arthroplasty has been shown to be less complex than total knee revision, this has yet to be corroborated for this group of patients. Further follow up of any failures will be necessary to determine whether defects in the replaced compartment necessitate the use of augments, bone grafting and/or stems.

Newer instrumentation has increased the appeal of the unicompartmental arthroplasty by allowing for small incisions with attendant lower patient morbidity and shorter hospital stays. Care must be taken when employing a minimally invasive approach to ensure that final implant fixation and alignment, keys to longevity of the construct, are not compromised. The long-term results of these techniques are not yet available, and common sense suggests that incision size should not be the dominant outcome measure of this technique. Similarly, as this procedure gains popularity, and despite the early experience at our institution, its routine application to younger patients awaits long-term documentation of success in this population.

Dr. Mark Froimson of the Department of Orthopaedic Surgery specializes in hip and knee replacement and minimally invasive techniques. He can be reached at 216/444-8784.

One of America’s Best

The Cleveland Clinic Department of Orthopaedic Surgery has a long history of excellence and innovation in medical and surgical care for those with musculoskeletal injuries and diseases. For the past several years, U.S. News & World Report has consistently ranked the Department of Orthopaedic Surgery among the nation’s top five orthopaedic programs in a survey combining physician polling with mortality rates and other data. The Cleveland Clinic has been designated as one of the top five hospitals in America since 1990 by U.S. News.
When Cleveland Cavaliers star forward LeBron James was elbowed in the face during the heat of a professional basketball game last December, the force was sufficient to fracture a facial bone. Moments after the injury, James underwent a physical examination by Cleveland Clinic team physicians, and within 30 minutes of the accident, James was undergoing a radiograph and CT scans of his face and skull at The Cleveland Clinic. Plastic surgeon Frank Papay, M.D., a specialist in facial fractures, was consulted, and he determined that surgical intervention would not be needed.

James was determined to return to play as soon as possible, so key to his treatment would be protecting the fractured facial bone and preventing pain and further injury or displacement. Through experience with these injuries in other athletes, Clinic physicians determined that the optimal treatment would be to design a protective orthosis to meet these goals and to allow James to continue playing without compromising his peripheral vision.

As soon as the swelling was reduced and absent was evidence of infection in the sinus or orbital areas, James was referred to Chris Piel, C.O., Chief of Orthotics and Prosthetics at the Clinic. In consultation with Cleveland Clinic orthopaedic specialists, Piel's department regularly creates custom orthoses for a diverse range of adult and pediatric problems, including arthritis, spina bifida, cerebral palsy and sports injuries to professional and amateur athletes.

For James, Piel designed a mask that fit snugly to protect and immobilize the facial bone without creating pressure points in other areas of the face. Constructed of a lightweight polycarbonate, the mask was sufficiently durable to withstand the rigors of a professional basketball game yet lightweight enough to be comfortable during wear. The mask was polycarbonate, the mask was sufficiently durable to withstand the rigors of a professional basketball game yet lightweight enough to be comfortable during wear.

The Department of Orthotics and Prosthetics was able to fabricate James’ mask within one day, facilitating his rapid return to action. James wore the mask for six weeks, playing in more than 20 games under careful medical supervision. He was permitted to discontinue use of the orthosis when the facial area could be palpated without causing him pain.

Dr. Richard Parker is Education and Fellowship Director of Cleveland Clinic Sports Health at The Head Team Physician to the Cleveland Cavaliers. He can be reached at 216/444-2992 or at parkerr@ccf.org.

Therapeutic Footwear Design: Effective Solutions using Computational Models
By Ahmet Erdemir, Ph.D. and Peter R. Cavanagh, Ph.D., D.Sc.

Cleveland Clinic orthopaedic specialists are using computational modeling to test therapeutic footwear designs for use in patients at high risk of ulceration, most commonly diabetic patients with peripheral neuropathy. Elevated and repetitive loading underneath the foot in these patients can cause skin breakdown, possibly leading to ulceration.

Therapeutic footwear can offer relief of plantar pressures. However, scientific guidelines for footwear prescription are not well defined. Barefoot and in-shoe plantar pressure measurements can be used to evaluate the efficacy of a footwear intervention once the shoe has been manufactured, but systematic testing of multiple design variables is difficult. For each design change, a new intervention needs to be manufactured and tested in a number of subjects. As a result, footwear selection in practice still relies on the experience of the health care provider and on trial and error.

Computational modeling offers an effective platform through which a large variety of footwear designs can be examined without the burden of high-volume human subject experimentation. The models can simulate variations in anatomy and footwear. For example, the insole geometry and material can be systematically varied, and the plantar tissue thickness can be changed to guide strategies for the prescription of therapeutic footwear.

One viable approach is finite element modeling, where complex structures are represented by many small geometric elements. When boundary conditions, loading and friction at the foot-shoe interface are defined, the models can predict stresses under the foot.

An integrated approach lays down the foundations of finite element simulations by computational and experimental research that provides the necessary input to develop models (see figure). The models include representations of foot anatomy, footwear geometry, soft tissue properties, footwear materials, foot kinematics and loading, and foot-footwear-ground interactions. Magnetic resonance imaging quantifies the anatomy of the foot to generate solid models of soft tissue and bones. Ultrasound provides the material properties of plantar soft tissue. Mechanical tests are used to obtain nonlinear stress-strain responses of footwear materials. Barefoot pressure measurements of a subject provide information on the baseline state of the individual foot and give input loading data for the model. Subject specificity is established by optimization protocols to map model-predicted pressure measurements to those measured experimentally. In-shoe pressure measurements using footwear manufactured according to the best model-predicted interventions are used directly in human experiments to validate the most effective designs for a given subject.

Design principles for primary prevention in low-risk diabetic feet (without significant complications) can be established by manipulating design variables in standard interventions such as thickness, layering and material for flat insoles, arch supports and off-the-shelf conforming insoles. For high-risk diabetic feet (complex feet with deformity and high focal pressure), guidelines for plantar pressure relief can be provided by simulating individualized designs, including metatarsal pads, bars, insole plugs, depressions, elevated arch supports and rigid rocker-bottom shoes.

Two-dimensional models have already provided guidelines for selection of insole thickness, material and conformity level to relieve heel pressures and for plug design for local pressure relief underneath the metatarsals heads. Using these models, it is possible to test new interventions within minutes. Designs for plantar pressure relief underneath the forefoot are evaluated by 3-D models, which can address load redistribution between the metatarsal heads and the longitudinal arch of the foot. These models provide a cost-effective framework for generating principles for therapeutic footwear design, allowing design to proceed without the lengthy trial-and-error process that often is conducted with the patient.

Dr. Ahmet Erdemir is a member of the Department of Biomedical Engineering. He can be reached at 216/444-9523.

Dr. Peter Cavanagh is Chairman of the Department of Biomedical Engineering and is Academic Director of the Cleveland Clinic Diabetic Foot Care Program. He has been involved in the study of diabetic foot complications for a number of years, including a term as chair of the American Diabetes Association Council on Foot Care. To speak with Dr. Peter Cavanagh, please call 216/444-6980 or 800/553-5056, ext. 56980. To refer patients to the Diabetic Foot Care Program, call 888/931-FOOT (3668).
Selective Cell Retention Technologies Offer Lower Morbidity than Autograft for Spinal Applications
By George Muschler, M.D.

Noved technologies, including improved bone graft substitutes, are continually being developed to overcome the limitation of autologous bone while offering fusion rates that are equivalent to autograft. To date, preclinical and clinical data demonstrate that selective cell retention technology, used with suitable graft matrices, represents an effective and low-morbidity alternative to autograft for spinal applications and fracture care. The CELLECT™ Selective Cell Retention system was introduced in 2002. Since then, its adoption rate by both orthopaedic and spine surgeons has grown substantially. Selective cell retention technology relies on the principles of an affinity column to populate graft material with high proportions of osteoprogenitor cells.

The CELLECT™ system was developed to be used with demineralized bone (Optium DBM), hydroxypatite-coated collagen (HEALOS) Bone Graft Replacement) or tricalcium phosphate granules (CONDUIT). Autologous bone marrow processed through these graft materials at a controlled specific rate allows for the attachment of osteoprogenitors to the graft matrix. A three- to four-fold increase in osteoprogenitor cell concentrations is typically captured within the graft materials compared with native bone marrow aspirate. The CELLECT™ system has been evaluated with demineralized bone and HEALOS in preclinical and clinical studies. Preclinical evaluations were performed in a canine model for spine fusion and in critical-size femoral defects. In this animal model, autograft generally heals successfully, but a non-grafted defect will result in a fibrous non-union. Similar healing patterns and non-unions were observed in defects filled with the CELLECT™-enriched grafts.

More recently, human clinical studies were initiated to evaluate the use of graft enriched through CELLECT™ in spinal fusion applications. Fifty-one patients were enrolled in an IRB-approved pilot study at five centers. All patients underwent a one- or two-level posteriorlateral fusion, with all but one having a concomitant interbody fusion. Bone marrow was aspirated from the iliac crest prospectively and passed through a mix of demineralized and mineralized allograft using the CELLECT™ system. Thus far, patient-reported outcomes demonstrate significant improvement in preoperative pain and disability. Fusion rates at 12 and 24 months are comparable with rates obtained with autologous bone graft. To date, 38 patients have completed a 12-month clinical follow-up including independent radiographic evaluation using plain lumbar radiographs. Eight patients have completed 24-month follow-up with both radiographic evaluation and CT scans with sagittal reconstruction. No serious adverse events resulted from the aspiration procedure.

At 12 months, visual analog scale (VAS) scores decreased by an average of 56.2 percent, 54.7 percent and 65.2 percent for back, right leg and left leg pain, respectively. Mean Oswestry Disability Index (ODI) scores decreased by an average of 53.7 percent compared with baseline. The postero lateral fusion rate at 12 months was 84.2 percent (32/38). At 24 months, VAS scores decreased by an average of 36.3 percent, 52.0 percent and 68.0 percent for back, right leg and left leg pain, respectively. Mean ODI scores decreased by an average of 36.7 percent compared with baseline. The posterolateral fusion rate at 24 months was 87.5 percent (7/8) based on CT scan. Two patients have required reoperation at a mean of 15 months post-op.

Dr. George Muschler holds appointments in the departments of Orthopaedic Surgery and Biomedical Engineering as well as in the Taussing Cancer Center and the Transplant Center. His specialty interests include adult reconstructive and joint replacement orthopaedic surgery, treatment of fracture nonunion and research in musculoskeletal tissue engineering. He can be reached at 216-444-5338 or at 800/353-3056, ext. 45338.

Dr. Joseph Iannotti, M.D., Ph.D., Chairman of the Department of Orthopaedic Surgery, are co-directors of the orthopaedic training program. They share a commitment to preparing young physicians for careers as clinician-researchers in orthopaedics. Dr. Cavanagh may be reached at 216/445-6980 or at cavanaphcf@ccf.org, and Dr. Iannotti may be reached at 216/445-3515 or at iannotj@ccf.org.

The grant recognizes The Cleveland Clinic’s strong interdisciplinary program in his or her orthopaedic research and wants to pursue further study in a specialty area. With MDs or PhDs who are invited to work in a specific area of orthopaedics with a dentists in orthopaedics; two one- to three-year experiences for post-doctoral students as its goal. At a higher level, the grant provides for two one-year opportunities for doctoral stu-

Orthopaedic Training Grant Prepares Physician-Scientists
By Peter Cavanagh, Ph.D., D.Sc., and Joseph Iannotti, M.D., Ph.D.

The Cleveland Clinic is the recipient of a Training Grant in Orthopaedic Science from the National Institutes of Health (NIH), establishing the Department of Orthopaedic Surgery as a training ground for forward-thinking, innovative leaders who will define the treatments of the future. The Clinic is one of the few NIH-funded centers to focus on the training of clinician-scientists in orthopaedics.

The grant provides for a number of research/clinical study opportunities each year. At the entry level, four medical students with an interest in orthopaedics spend eight to 10 weeks in the department and at the Lerner Research Institute over the summer. This has typically been an ideal interface between the Department of Orthopaedics and Cleveland Clinic to Host 3rd Annual Medical Innovation Summit: Bench to Bedside and Back, October 24-26, 2005

The Cleveland Clinic will once again host the Medical Innovation Summit, which is expected to draw over 800 top-level industry executives, entrepreneurs, investors and clinicians. This year’s Summit, scheduled for October 24 through 26, will focus on orthopaedic medical innovations.

World-class presenters will highlight new technologies and trends in orthopaedics and other high-growth clinical areas, venture investing and the challenges related to getting products to market. Additionally, for the third year in a row, live interactive surgery will be presented.

The 2005 Medical Innovation Summit, titled Bench to Bedside and Back, will feature internationally recognized speakers and will explore in detail the blurring of traditional boundaries between medical industry segments and clinical specialties that are driving increased market consolidation, the emergence of new business models and the evolution of imaginative forms of collaboration.

The Cleveland Clinic Medical Innovation Summit will include presentations and interactive panel sessions on specific medical innovations, technology drawn from multiple disciplines and convergence across traditional boundaries. Speakers include Nervt Gingrich, Former Speaker, U.S. House of Representatives; Michael Porter, Ph.D., Harvard Business School; Arthur Collins, CEO, Medtronic; Steve MacMillan, CEO, Stryker; Michael Dormer, Worldwide Chairman of Medical Devices for Johnson&Johnson; and Sir Christopher O'Donnell, CEO, Smith & Nephew, plus many others. The event will be held at the InterContinental Hotel & MBNA Conference Center on the main campus of The Cleveland Clinic (ranked among the top 4 hospitals in U.S. News & World Report’s annual “America’s Best Hospitals” survey), in Cleveland, Ohio.

For more information on the Summit, including a complete list of speakers for 2005, visit www.clevelandclinic.org/innovations.
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eRadiology: World Class Imaging at Your Doorstep

By Michael Recht, M.D.

Subspecialized medical care is the standard of care in medicine. No one other than an orthopaedic surgeon would perform an anterior cruciate ligament reconstruction or arthroscopic repair of a rotator cuff tear. However, it is still common for general radiologists with no subspecialized orthopaedic training to interpret the images that lead to these procedures.

This lack of subspecialized radiology interpretations has been a cause of concern for many orthopaedic surgeons and can result in suboptimal care. Now, through the use of new developments in information technology systems, the Cleveland Clinic Department of eRadiology offers subspecialized radiology interpretations to orthopaedic surgeons anywhere in the country. In addition, we work with orthopaedic surgeons to provide these services as part of their practice, maximizing convenience for the patient while maintaining the highest standards of patient care.

The Department of eRadiology began as a natural progression of the Cleveland Clinic’s need to integrate seven hospitals, 14 family health centers and several outpatient imaging centers into one cohesive radiology service model. The result was the installation of an integrated Radiology Information System (RIS) and Picture Archival Communications System (PACS), thus enabling the easy movement of patient data and images anywhere within the network.

Over the past five years this model has grown to include more than 30 separate imaging locations in 12 states, and radiologists perform in excess of 50,000 exams annually. Modalities include MRI, CT and nuclear medicine, including PET scans.

Each of our client locations is integrated with our radiologists via a high-speed virtual private network that allows Cleveland Clinic radiologists to receive each exam in real time, while conforming to HIPAA regulations. We train technologists at our client locations in the use of the appropriate modalities, as well as in our RIS and PACS systems. We provide exam protocols for every procedure based upon patients’ medical indications and histories. If the technologists uncover an unexpected or major finding, they send us images while the patient is having the exam. This way, the exam can be modified without having to call the patient back for additional imaging. In addition, the referring physician can be notified before the patient leaves the imaging center.

Radiology reports are typically available within 24 hours, with STAT reports available upon request. If unexpected findings surface, our radiologists call the referring physician immediately. Although our client locations can print films, our PACS system enables the site to burn a CD of the images. The CD can be used for on-site archival or given to the patient. In addition, the images and reports can be made available to the referring physician via Internet access using a secure password and ID number, enabling the referring physician to review their patients’ results from anywhere.

Many orthopaedic practices are bringing imaging services in-house to improve access, scheduling and patient convenience. eRadiology can ease this process by providing site design and construction, equipment selection and procurement, technologist training, informatics and examination interpretations.

The radiologists associated with the Department of eRadiology provide services full time to our client locations; they are available throughout the day for consultations and follow-up with the referring physician, making our services truly integrated with the physician practice.

Dr. Michael Recht, Chairman of the Department of eRadiology at The Cleveland Clinic, is available to discuss these services with you. Physicians may call 216/444-2285 or e-mail at rectm@ccf.org.

Director of Clinical Outcomes Joins the Department of Orthopaedic Surgery

Boris Bershadsky, Ph.D., joined the Department of Orthopaedic Surgery in June as the Director of Clinical Outcomes. Dr. Bershadsky brings 20-plus years of academic and business-experience in biomedical, bioengineering and health care research to the department to greatly expand and further develop the organized program and infrastructure for the collection, analysis and publication of clinical outcome data. This outcome program will assess all patients having surgery in the Department of Orthopaedic Surgery, focusing on joint replacement, sports injuries, systemwide monitoring of complications and adverse events and development of clinical trials to evaluate new surgical treatments and devices. The goal over the next couple of years will be to establish a clinical outcomes program across the entire Cleveland Clinic Health System. Dr. Boris Bershadsky can be reached at 216/444-5955.