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Hospital Efforts Balance Quality Of Life and Patient Care

Quality of life (QOL) is a "big picture" concept. It necessarily reflects traditional assessment methods, duly regarding the significance of reviewing X-rays and studying test results. However, the Division of Pediatric Orthopedic Surgery within the Department of Orthopaedic Surgery at Morgan Stanley Children's Hospital of NewYork-Presbyterian/Columbia is focusing on another component of QOL assessment—the total effect that clinical intervention has on the functional capacity and overall QOL in pediatric patients with neuromuscular conditions.

"Keep your eye on the patient, not on the x-rays," noted Michael G. Vitale, MD, MPH, in explaining the underlying philosophy behind the effort. According to Dr. Vitale, surgeons traditionally focus on examining the so-called "process" end points such as X-rays when assessing patient progress. This type of focus often fails to incorporate the examination and review of other important aspects of patient health and outcome, including lifestyle, care needs, and impact of the patients' condition and treatment on family and caregivers.

The research at NewYork-Presbyterian/Columbia aims to introduce a multifaceted means of exploring the full range of outcomes that clinical

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Surgeons Explore Use of Total Resurfacing in Hip Replacement

Relatively young and physically active candidates for total hip arthroplasty (THA) surgery may benefit from a cutting-edge procedure that preserves bone and provides improved long-term stability function with less risk for dislocation. The procedure, known as total hip resurfacing (THR), can be used for patients suffering from osteoarthritis, rheumatoid arthritis, and advanced avascular necrosis.

Improved prosthetic designs and new techniques have improved outcomes in hip replacement.

Resurfacing procedures for hip arthroplasty are not new. Historically they have had higher failure rates, due, in part, to flaws associated with prosthesis design that can lead to sticking, socket loosening, and metallosis. Now, improved designs and advances in metallurgy appear to have resolved many of these problems. The

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Studies Investigate Evidence-Based Approach for Osteoporosis

For orthopaedic surgeons, management of osteoporosis-related fracture requires medical as well as surgical intervention. Drug therapy and protective strategies have the potential to help heal and prevent osteoporotic fracture. But which medical interventions really work?

To answer that question, 3 new studies are in progress at NewYork-Presbyterian Hospital/Columbia University Medical Center. These well-controlled studies are designed to provide Level 1 evidence—the highest degree of evidence in clinical trials.

Two studies will assess the effect of the osteoporosis drugs, risedronate or teriparatide, on fracture healing. The third study will test the use of lighted slippers to prevent falls. By generating strong data, these studies will have important ramifications for the future of clinical practice in osteoporosis.

"There are powerful drugs and other interventions out there," said Melvin Rosenwasser, MD. "We want to know whether these interventions really alleviate suffering." If they do, he added, the interventions tested could substantially reduce the human and economic costs of osteoporosis.

A clinical x-ray of a colles wrist fracture in a post-menopausal woman. This patient represents the treatment population for the teriparatide study at NewYork-Presbyterian/Columbia.

"These are not minutiae," noted Dr. Rosenwasser. "These are substantial end points."

One of the studies will examine whether risedronate accelerates or decelerates hip fracture healing. The study will also evaluate bone density in the contralateral hip and the movement of orthopedic hardware in the healing hip. It is funded by a grant from the Orthopaedic Trauma Association.

According to the principal investigator, Carolyn Becker, MD, the most important contribution of the research will be to expand "our understanding of optimal post-fracture care of patients with osteoporotic fractures."

"Our current management of these patients is unacceptable," said Dr. Becker. "Most leave the hospital without any medical management. This is analogous to admitting a patient with a heart attack, then sending the patient home without any interventions for decreasing cardiovascular risk factors."

Risedronate is a bisphosphonate, a class of drugs that slows the resorption of bone. This mechanism of action prevents bone loss in osteoporosis and associated fracture. However, the *healing* of fractures is a dynamic process that requires bone resorption for remodeling of the callus that forms post-fracture, raising the question of whether bisphosphonates help or hinder fracture healing. Animal studies show that bisphosphonates alter the fracture callus; the bone formed is less mature, but the callus is larger than normal, with excellent bone strength.

Depending on the results of the NewYork-Presbyterian/Columbia study, clinicians will gain evidence for or against the use of risedronate immediately after fracture. As Dr. Becker suggested, the study can help determine whether antiresorptive therapy "should be started as soon as possible after fracture or delayed for 3 to 6 months." The findings may also contribute to a new algorithm for post-fracture management in osteoporosis.

Columbia researchers are also participating in a trial to see whether

teriparatide can hasten the healing of distal radius fractures in postmenopausal women. Teriparatide is the human parathyroid hormone fragment, PTH (1-34). It regulates metabolism of calcium and phosphate, stimulating an increase in bone mineral density that can reduce the incidence of osteoporotic fracture.

"Teriparatide works by a totally different mechanism than drugs like risedronate, which slows bone resorption," noted Dr. Becker. "Teriparatide 'turns on' osteoblasts, the cells that build bone, whereas antiresorptive agents 'turn off' osteoclasts, cells that destroy bone."

In animal models, teriparatide increases callus area, strength, and density at fracture sites. The new study will be the first to explore whether teriparatide provides comparable benefits to patients with wrist fracture. In Dr. Rosenwasser's view, both the teriparatide and risedronate studies seek to show whether drug intervention can "improve on nature. If an intervention can change the natural history of fracture—if it can take weeks off the healing process—then patient comfort should improve and direct and indirect medical costs should go down."

Of course, the best way to manage fractures is to prevent them from occurring in the first place. Among older adults, falls are a leading cause of fracture. Historically, clinicians have tried a variety of techniques to prevent fall-related fractures—from balance-enhancing *Tai Chi* to hip protector pads. But prevention techniques only work when patients are willing to use them. For this reason, Dr. Rosenwasser is heading a research team to determine the efficacy of a simple, convenient intervention to prevent nighttime falls—battery-powered, lighted slippers.

Dr. Rosenwasser's study will compare ambulation with slippers on versus ambulation with slippers off, using the Timed Get-Up-and-Go test—a reliable assessment tool that correlates well with balance, gait speed, performance of normal daily activities, and ability to go outside alone safely. Researchers will also collect patients' subjective responses on the acceptability of the slippers, the sense of security they inspire, and patients' willingness to use the slippers on their own.

"This research identifies real clinical problems," he said, "and aims to make a tangible difference in solving those problems."

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NewYork-Presbyterian/Columbia Orthopaedics Editorial Board

Evolutionary Focus Uncovers Keys to Forefoot Disorder, Collapsed Arch

Evolutionary explanations can spur clinical insights into modern disorders of the foot. Early in the 20th century, pioneering research by Columbia University anatomist Dudley Morton analyzed and compared the architecture of the human foot with that of other primates. Today, Justin Greisberg, MD, offers a similarly informed interpretation of various foot disorders.

The foot and ankle constitute a complex, imperfect machine, an adaptation to bipedalism developed through the evolution of an appendage that in primates was flexible. "A lot of the foot problems we see in modern humans can be considered atavistic," said Dr. Greisberg. "For millions of years, our ancestors lived an arboreal lifestyle, with a foot that was as flexible as a hand. Only in very recent times has the human foot traded flexibility for stability in pursuit of bipedal gait."

Bunions represent a prime example. One of the most common of forefoot disorders, they are popularly blamed on tight shoes and high heels. But the reality is more complex. Bunions sometimes appear in young children and are found in populations that never wear shoes. Whether the cause is a congenital defect or inherited trait, most cases of hallux valgus deformity can be traced to the evolution of the first metatarsal. The ape foot features a mobile hallux that makes the whole structure prehensile and highly mobile, able to grasp and navigate tree branches. In contrast, the human foot has a stable and rigid first metatarsal, adapted to weight bearing and bipedalism.

"When a 25-year-old woman walks into your office with a large bunion, telling you her mother had one and her grandmother had one, and she never wore high heels, you can't go blaming that on women's shoes," said Dr. Greisberg. "She's got an inherited defect in her foot."

X-ray of bunions: Researchers now believe they are a genetic defect.

Using screws instead of sutures, the lapidus procedure can improve outcomes.

In addition to its diagnostic value, evolutionary-based insight can have an impact on treatment choices. Patients suffering from bunions, for instance, may best be treated by a form of foot reconstruction surgery called lapidus arthrodesis, which stabilizes the base of the first metatarsal.

Similarly relevant for foot pathology is the case of the longitudinal arch. The arch works both as a shock absorber and a bridge that allows nerves and vessels to reach the forefoot without being crushed while walking. "If you look at a lateral x-ray of a human flatfoot, it looks very much like that of a gorilla," said Dr. Greisberg. In terms of evolution, he added, "the foot developed first and allowed the ape to walk upright, freeing up the hand; the human brain expanded with the hand." The weight-bearing foot, in fact, is the key event in the development of the modern human being.

Dr. Greisberg is critical of overreliance on traditional foot surgery to correct both bunions and fallen arches. Typical bunionectomies, although appropriate in some cases, actually create a secondary deformity to treat the first. Similarly, the traditional triple arthrodesis for flatfoot, which involves fusing all the joints, often results in a postoperative complication in which the patient's foot is stiff and does not function well. A more contemporary answer is to address the root pathology by realigning and stabilizing the arch joints. In contrast to "nip and tuck" foot surgery, these surgical solutions restore normal foot function.

The lapidus procedure, although gaining in popularity, remains "controversial among orthopedic foot surgeons," said Dr. Greisberg. With relatively long convalescence periods and some risk, the lapidus "has been considered too extreme of a procedure. But there's a new generation of us that think it can be a solution for many of the more extreme feet out there."

Today, careful patient selection and the use of stainless steel screws instead of sutures have considerably reduced the complication rate, which was as high as 15% 10 years ago, to less than 5% today. "When you study the foot from an evolutionary perspective, you can see what the foot is supposed to do," he noted. "And now you can see the procedures that are going to provide better long-term results and more normal foot structure."

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New Approach to Rotator Cuff Repair Focuses On Improved Biomechanical Stability

An innovative arthroscopic procedure for rotator cuff repair may substantially reduce failure rates for one of the most common causes of shoulder pain and disability. Refined by Columbia researchers at NewYork-Presbyterian Hospital, the "transosseous equivalent" repair technique translates into clinical practice by way of recent orthopaedics research, highlighting the significance of a sharpened focus on the basic biology of tendon healing and repair.

"From a biomechanical standpoint I think we've almost gotten to the point where we have the problem solved with the new technique being able to provide the best biomechanical environment for the tendon to heal," said Christopher S. Ahmad, MD.

Orthopedic research at NewYork-Presbyterian/Columbia currently includes investigations into the biomechanics of repair and the underlying biochemistry of the healing process. Failure in tendon-to-bone healing after surgical intervention has long frustrated surgeons and patients, though not for lack of choice among available procedures. Surgeons now perform open, mini-open, and arthroscopic repairs.

"Rotator cuff repair has been in a state of evolution in the last few years," said Louis U. Bigliani, MD. "It continues to improve with newer and better techniques that are achieving secure fixation on the great tuberosity."

The abiding problem of post-repair stability has generated considerable scrutiny, but only recently have investigators moved beyond a focus on the strength of repair to explore the impact of interface motion between tendon and bone. Last year, Dr. Ahmad and colleagues performed a series of laboratory experiments to compare suture anchor fixation and transosseous suture fixation in terms of motion and pressure distribution. They employed a cadaveric model and recorded data on film to be digitally analyzed, extending a research technique first employed at the Center for Shoulder, Elbow and Sports Medicine, and widely emulated since.

One of their studies (*Am J Sports Med* 2005;33:1154-1159) demonstrates that transosseous suture repair (TSR) creates significantly improved contact and overall pressure distribution. Another paper in the same journal (*Am J Sports Med*, 2005;33:1667-1671) shows that TSR offers superior fixation with less interface motion.

> "The next breakthrough in rotator cuff healing is going to affect the actual biology."
>
> —Christopher S. Ahmad, MD

"The tendon heals to the tuberosity by developing some fibrovascular tissue interface," said Dr. Ahmad. "And, in that interface, the collagen of the tendon will then attach to the bone."

These contributions to the biomechanics of footprint repair have spurred an adaptation by which the transosseous suture technique, an open repair, can be done arthroscopically; this is a desirable innovation that enables better visualization and assessment opportunities. Dr. Ahmad details the "transosseous-equivalent" procedure, currently in use at NewYork-Presbyterian Hospital, in an article soon to be published in *Orthopaedics Today.* He characterizes the surgery as "the most sophisticated and current way of fixing a rotator cuff arthroscopically." Follow-up results from ongoing clinical studies are expected in 1 to 2 years.

The Center for Shoulder, Elbow and Sports Medicine and The Center for Orthopaedic Research at NewYork-Presbyterian/Columbia have also made great strides in understanding the biology of rotator cuff repair, through innovative research on the role of inflammation in rotator cuff disease. Beyond surgical repair, the tendon-to-tuberosity problem underscores the significance of biochemical and molecular issues around rotator cuff injury. It has long been known that the subacromial bursa is a complex structure, but the role of inflammation remains to be clarified.

"We think that [the] bursa gets inflamed as a result of tendinitis or tendon tears," said Theodore A. Blaine, MD. "That inflammation leads to pain and prevention of the tendon from healing."

Dr. Blaine and colleagues have tested this hypothesis in a series of papers that determine the presence of molecules known to be proinflammatory in the subacromial bursa. These include cytokines, proteases, and cyclooxygenase enzymes. In an article published last year (*Arthroscopy* 2005;21:1076), they compared histologic evidence from patients with full-thickness rotator cuff tear and controls without tear (most of whom were undergoing the surgery for instability). Both inflammatory cytokines and the cyclooxygenase enzymes (COX-1 and COX-2) were present in the group with rotator cuff tear but were largely absent from control patients; moreover, prevalence correlated with severity. These results suggest that bursal resection may help reduce inflammation and, by underscoring the role of inflammation in the subacromial bursa, Dr. Blaine looks toward an improved grasp of the biochemical underpinnings of rotator cuff disease with a view toward better treatment options and targeted therapeutics.

"The first aim is to understand the actual pathophysiology of rotator cuff disease. The second is to find new therapeutics, new drugs, and new treatments," he noted. Some novel and important new molecules have already

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intervention can have on QOL. In order to best serve patients, physicians must carefully consider the myriad pontential effects that treatment of any disease, such as cerebral palsy, can have on QOL of affected children. Once the appropriate treatment is determined, physicians then review the impact of treatment and weigh the benefit to the patient.

Numerous inherent challenges are involved in the assessment of health-related QOL in children, according to David P. Roye, MD. "Children are rapidly changing, and adapt in special ways to disease and disability," he said. "Furthermore, many of our patients cannot directly give information about their health, so we need to rely on the view of the parent or other caretaker."

In response to these challenges, the Pediatric Orthopaedic Research Group at Morgan Stanley Children's Hospital of NewYork-Presbyterian is pioneering efforts to address the specific needs of its patients. Molding opinion in this area of research, the group has contributed numerous publications, slowly refining options for assessing health-related QOL in children.

Dr. Vitale, along with co-investigators and partners Dr. Roye and Joshua E. Hyman, MD, are currently completing a multi-year study that aims to change the method of evaluating, and perhaps ultimately treating, children with cerebral palsy. Entitled "A Study of Quality of Life and Care Giver Burden in Children With Neuromuscular Disease," the research initiative will create a clinical instrument that will quantify QOL in children before and after treatment of several debilitating neuromuscular conditions.

The study design allows for multivariate analyses of important factors such as age at initial intervention. As a practical consideration, the study has created 3 age-based classes of patients—infants (from birth to 2 years old), toddlers (2 to 5 years old), and children (from 5 years)—which allow different foci on milestone achievement. The study methods include a comprehensive examination, enabling a team of physical therapists led by Debra Krasinski, PhD, to evaluate patient status.

> "Keep your eye on the patient, not on the x-rays."
>
> *Michael G. Vitale, MD, MPH*

One of the specific issues examined by investigators is the impact that neuromuscular disease and subsequent treatments might have on the socialization of the child. In connection with this issue, investigators also review and evaluate the broader effects of patient treatment and responses on the family unit. According to Dr. Hyman, it may be difficult or impossible for an affected child to respond appropriately to questions posed by physicians or investigators. Enlisting help by observation from family members or caregivers offers important insight into a child's QOL which is not or cannot be communicated.

The investigators acknowledge that few people truly recognize the tremendous emotional, physical, and financial impact that caring for a child with significant neuromuscular disease can have on the family. "Our research has documented these issues for the first time in this population and suggest that clinical intervention, such as correcting a crooked spine, can have a profound and meaningful impact on not only the child, but on the family," said Dr. Hyman.

Added Dr. Roye, "While we see the need to explore broadly defined issues related to [QOL] and family function, we continue to recognize the importance of traditional outcome measures—things like time for bone healing, transfusion rates, and x-ray findings."

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advances leave THR with a new and potentially vibrant future.

Performed using a number of techniques (a minimally invasive approach is growing in popularity), standard THA surgery entails the installation of an artificial femoral head, neck, and acetabulum, with a stem inserted deep into the medullary canal of the hollowed-out femur. For many patients, this procedure is "probably the best operation that's ever been invented, in terms of reliability, reproducibility among different surgeons, and reliable release from pain," noted William Macaulay, MD. That said, Dr. Macaulay and others believe that a significant minority of patients could benefit, over the long term, from THR instead of replacement.

Total hip resurfacing may be a highly desirable alternative for younger patients… to maintain maximum activity, range of motion, and flexibility.

"There are certain reasons to think, particularly in young and active individuals, that invading the proximal third of the thigh bone may not be the best thing for them," said Dr. Macaulay.

Because it preserves the femoral head and neck, and avoids the need to implant a stem deep within the bone, THR may be a highly desirable alternative for younger patients who want to maintain maximum activity, range of motion, and flexibility. With standard hip replacement, there is a minor, but not negligible, risk of dislocation. With THR, the larger size of the implanted cap head reduces this risk while bone preservation improves prospects for revision, if necessary.

A number of medical device manufacturers are currently developing versions for use in the United States. All involve the combined use of a cobalt–chrome cast metal cap and a femoral head cap (with short guide stem) and a cobalt–chrome socket. Individually, these devices have been approved by the FDA, but their combined use in THR awaits final action. A small number of surgeons with special training, including Dr. Macaulay, have begun performing the procedure on a compassionate and/or off-label use basis.

Most patients requiring hip surgery can have conventional hip replacement. In some cases, however, total resurfacing may be indicated. For a patient with preexisting hardware within the femoral shaft, for example, or other kinds of altered thighbone anatomy, THR would be the procedure of choice. With THR, said Dr. Macaulay, "we basically tell patients after surgery, 'You have no limitations. Move the hip any way you want, right from day 1.'"

Case Capsule

A 36-year-old man, L.S., suffering from osteonecrosis of both hips, had previously undergone successful replacement surgery on the left side when he arrived at the Hospital for treatment of the current problem. Within several months of the previous surgery, increasingly severe pain on the right side made a second surgery mandatory. For this procedure, Dr. Macaulay and L.S. decided on THR. The bone-preserving implant procedure was carried out without complications. Instead of replacing the femoral head, it was reshaped and a small guide stem, topped with a metal cap, was set into the pelvic joint resurfaced with a metal shell; the rough surface of the shell cup would enable bone to grow into the implant. It should be noted that the procedure has its own learning curve, and the surgeon, while preparing the femoral head, must avoid notching or creating defects in the femoral neck.

Just as with his previous conventional total hip replacement, L.S. was home on the second day after surgery. One feature of THR is that recovery time is shorter than with all other forms of hip replacement surgery, including minimally invasive procedures. Return to full activity can be expected to take 2 1/2 weeks with THR, as opposed to as long as 4 weeks with THA.

Several months after the operation, L.S. claimed that the right-side hip seemed to heal faster and feel better than had been the case with the standard hip replacement on his left side. The hip, he said, felt more like his own.

"I felt almost total relief just after surgery," he recalled, adding that within 1 to 2 days, he detected, in welcome contrast with his earlier operation, greater mobility and strength in his right leg. "The recovery was fantastic."

This subjective assessment is instructive inasmuch as conventional wisdom holds that satisfactory fixation within the femoral canal and a stable hip replacement, which essentially provides the patient with the same engineering as the natural skeleton, should in principle feel like a normal hip. However, said Dr. Macaulay, "when you keep the neck of your own femur, which you do with this procedure, there's less room inside the joint space for the collection of blood and fluids after the surgery." With the body resorbing less fluid, it is plausible to suppose the patient might feel better faster.

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been identified. These molecules, which may serve as specific targets for new drugs and hopefully will replace the need for non-specific anti-inflammatories such as COX-2 inhibitors, were outlined in a recent article (*J Shoulder Elbow Surg* 2005;14:84S-89S) and are the focus of another publication in an upcoming 2006 issue of the *Journal of Orthopaedic Research*.

Indeed, improved understanding of the basic biology of healing may be expected to win increasing importance both in its own right and in relation to surgical outcomes. William N. Levine, MD, is engaged in basic research into the interface between soft tissue and bone that he expects will translate into clinical advances. Substance and form remain to be determined, but current candidates include plasma-rich proteins and growth factor.

"The future will hold some kind of adjunct that we, as surgeons, will be able to place between the tendon and the bone, and then repair the tendon to the bone," he said. "The first goal is to get rid of pain. As surgeons, we'd like to restore anatomy and we'd like to restore function, which is multifaceted. Not just quality of life during activities of daily living but, in the ideal setting, back to sports, back to the activity level that the patient would desire. That's the ultimate goal."

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