

CHILDREN'S HOSPITAL-BOSTON: SUMMARY OF PROJECTS AT THE CLINICAL EFFECTIVENESS RESEARCH CENTER

PATRICIA L. CONNELL, M.P.H.

DEPARTMENT OF ORTHOPAEDIC SURGERY, CHILDREN'S HOSPITAL, BOSTON

INTRODUCTION

The Children's Hospital Orthopaedic Clinical Effectiveness Research Center (CERC) has been in existence for five years. The research group's mission is to improve the effectiveness of management of musculoskeletal conditions in children and adolescents via applied epidemiologic research. The goals are to provide epidemiologic and biostatistical support for pediatric orthopaedic clinical research, to apply advanced epidemiologic methods to pediatric orthopaedic clinical research, and to develop independent fields of inquiry into musculoskeletal conditions affecting public health. The dedicated and hard-working members of the CERC research team, which includes attendings, fellows, residents, nurses and study coordinators, have made it possible for the various orthopaedic programs to carry out more than two dozen high-quality clinical research projects during the last year. Moving forward, we will strive to conduct research utilizing study designs and methodology that result in higher levels of evidence, allowing us to practice truly evidence-based-medicine and to provide our patients with the best clinical care possible.

SPINAL PROGRAM

John B. Emans, M.D., Daniel Hedequist, M.D., M. Timothy Hresko, M.D., Lawrence I. Karlin, M.D., Young-Jo Kim, M.D., Ph.D., Brian Snyder, M.D., Ph.D.

SPINE STUDIES SPONSORED BY THE SPINAL DEFORMITY STUDY GROUP

The mission and purpose of the Spinal Deformity Study Group (SDSG) is to create a means and forum whereby multi-center studies can be developed and conducted both efficiently and effectively. The SDSG is comprised of fifty national and international spine surgeons from 35 participating sites worldwide. Drs. Emans, Hresko and Hedequist are members of the SDSG.

Patricia Connell M.P.H. is Manager of the Clinical Effectiveness Unit at Children's Hospital.

Address correspondence to:

Patricia Connell, M.P.H.
Clinical Effectiveness Research Center Department of Orthopaedic Surgery Children's Hospital Boston
300 Longwood Avenue
Boston, MA 02115

(SDSG) PROSPECTIVE PEDIATRIC AND ADOLESCENT SCOLIOSIS STUDY

This is a prospective multi-centered study focused on the outcomes of pediatric and adolescent idiopathic scoliosis. The main purpose of this observational study is to develop a prospective comprehensive radiographic and clinical database on consecutively treated pediatric and adolescent scoliosis surgical cases to assess outcome measures in patients with operative idiopathic scoliosis being treated with current surgical techniques. A secondary objective of this study is to obtain data on currently available surgical approaches to treat idiopathic scoliosis in the thoracic, thoracolumbar, and lumbar spine.

(SDSG) PROSPECTIVE PEDIATRIC AND ADOLESCENT KYPHOSIS STUDY

The main objective of this prospective multi-center, observational study is to assess outcome measures in pediatric and adolescent patients with kyphosis, who are being treated non-operatively or operatively with current surgical techniques. Secondly, data on currently available surgical approaches to treat pediatric kyphosis in the thoracic and/or thoracolumbar spine will be collected.

(SDSG) PROSPECTIVE STUDY OF DEFORMITY MANAGEMENT AND PULMONARY FUNCTION IN EARLY-ONSET SCOLIOSIS

The goal of this prospective multi-center study of children with "idiopathic" scoliosis is to document concomitantly: (1) control of spinal deformity, (2) growth of the thoracic spine longitudinally and transversely at a rate commensurate with the number of vertebrae involved, and (3) increasing lung volume, absolute and relative to body size.

(SDSG) THE EFFECT OF SURGERY ON SAGITTAL SPINO-PELVIC MEASURES OF BALANCE IN DEVELOPMENTAL SPONDYLOLISTHESIS AND ITS RELATION TO CLINICAL OUTCOME

The short-term goal of this prospective multi-center, observational study is to confirm the predictive value of sagittal spino-pelvic measurements in the surgical treatment of L5-S1 developmental spondylolisthesis. The long-term objective is to determine the optimal surgical treatment for L5-S1 developmental spondylolisthesis based on x-ray evaluation of sagittal trunk balance and functional outcome.

SERUM LEVELS OF NICKEL AND CHROMIUM AFTER INSTRUMENTED SPINAL ARTHRODESIS

This cross-sectional study was undertaken to investigate the relationship between factors such as age, gender, pain, time from surgery, length of arthrodesis and level of arthrodesis to serum metal ion levels after instrumented spinal arthrodesis. An analysis revealed that time from surgery was the only significant multivariate predictor of nickel and chromium serum

levels. The levels were significantly higher than normal in the first two years after a spine fusion, then declined rapidly but remained above normal four years after surgery. The metal ion levels seen in this study are comparable to that seen after total joint arthroplasty. This investigation will be followed by a prospective longitudinal study, which is currently in development. Baseline and follow-up measurements of serum levels of nickel, chromium, titanium, aluminum and vanadium will be performed in patients and controls.

Publication: Kim YJ, Kassab F, Berven SH, et al. Serum levels of nickel and chromium after instrumented posterior spinal arthrodesis. Spine 2005;30:923-6.

MOLECULAR BASIS OF HUMAN VERTEBRAL SEGMENTATION DEFECTS

This project is a pilot study being conducted by Children's Hospital-Boston and the Stowers Institute for Medical Research and will help facilitate research on vertebral segmentation defects. The major goals of this project are to: (1) identify genes associated with congenital scoliosis by sequencing genes known to be associated with vertebral anomalies in mouse models, (2) explore the environmental exposure and familial history of children with severe congenital scoliosis, (3) evaluate the association between Delta-like 3 and MESP2 mutations and Jarcho-Levin syndrome in sporadic cases (non-familial cases) and severe cases of congenital scoliosis, and (4) identify mutations in newly identified genes involved in somitogenesis in mouse and chick embryos in severe cases of congenital scoliosis.

CHEST WALL AND SPINE DEFORMITY REGISTRY

Patients in this multi-center cohort study will be followed until maturity. The major goals of this study are to: (1) describe the characteristics of chest wall and spine deformities and their associated anomalies, (2) describe the progression of these deformities before treatment, (3) describe the treatments received, and (4) analyze the short- and long-term outcomes of these treatments.

HALO TRACTION AND INSERTION OF EXPANDABLE DEVICES FOR THE TREATMENT OF SEVERE PEDIATRIC SPINAL DEFORMITIES

The major goal of this retrospective study is to document the Children's Hospital-Boston experience with halo traction and insertion of expandable devices in children with severe scoliosis or kyphosis. The interrelationships between duration of traction, patient weight and surgical releases, and the effect of traction on bone mineral density will also be examined.

SPORTS MEDICINE AND ORTHOPAEDIC TRAUMA PROGRAM

Lyle J. Micheli, M.D., Mininder Kocher, M.D., M.P.H., Pierre D'Hemecourt, M.D.

PIGMENTED VILLONODULAR SYNOVITIS OF THE KNEE: POST-OPERATIVE FUNCTIONAL ASSESSMENT OF ADOLESCENTS.

Pigmented villonodular synovitis (PVNS) is a rare, idiopathic disease with no universally accepted method of treatment. The aim of this prospective study is to add to the limited literature by evaluating the post-operative outcomes of adolescents treated for PVNS of the knee. Specifically their functional

outcomes using standardized knee instruments such as the IKDC Subjective Knee Evaluation Form, Tegner Activity Scale, and the Lysholm Knee Score will be used.

EVALUATION OF NON-OPERATIVE TREATMENT FOR JUVENILE OSTEOCHONDRITIS DISSECANS OF THE KNEE

Data for this prospective cohort study are being collected at Children's Hospital-Boston (CHB) and the Children's Hospital of Philadelphia (CHOP). The main objective is to compare three different methods of non-surgical treatment of Juvenile Osteochondritis Dissecans (J OCD) of the knee to see which method leads to quicker healing and return to regular activity. Treatment at CHB will consist of physical therapy alone or knee immobilization with an unloader brace and will be compared to treatment at CHOP which involves casting followed by physical therapy.

PROSPECTIVE MULTI-CENTER PEDIATRIC ACL RECONSTRUCTION STUDY

This cohort study will be conducted in three phases, the first of which is already underway. *Phase 1:* Children's Hospital-Boston is conducting a series of cognitive interviews to determine whether items on the International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Form are interpreted by children and adolescents, as intended. The psychometric performance of this form has been evaluated in adults with a range of knee conditions, but its usefulness as an outcome instrument in younger populations is not yet established. The form will be modified, as needed, based on the results of these interviews. *Phase 2:* The psychometric properties, including reliability, validity, and responsiveness of the new form version will be further validated in children and adolescents with a variety of knee ailments. *Phase 3:* The multi-center study, which will be led by Children's Hospital-Boston is currently in the development phase. The main objective of the study will be to determine the most effective surgical and non-operative treatment methods for ACL injury in pre and early pubescent children. Patient outcomes will be assessed using the new version of the IKDC Subjective Knee Evaluation Form.

PROSPECTIVE STUDY OF SPORTS INJURIES IN NEW ENGLAND UNIVERSITY RUGBY CLUBS

Rugby has flourished on American university campuses. In recent years there have been efforts to get rugby recognized by the NCAA as an official collegiate sport. A major impediment to acceptance has been concern about the relative safety of the sport. Thus, the main goal of this study is to determine the incidence of collegiate rugby injuries in the United States and to characterize these injuries. The incidence of injury will be compared to other collegiate sports in the United States and to rugby injuries internationally. The secondary aim is to explore relationships between injury and player experience, gender, player position, coaching, field surface, weather conditions, conditioning, and equipment.

PROSPECTIVE STUDY OF ADOLESCENT SPONDYLOLYSIS PATIENTS TREATED WITH ELECTRICAL BONE GROWTH STIMULATORS

The primary aim of this two-armed, single-blinded, randomized controlled trial is to determine whether standard of care treatment plus electrical stimulation helps bones heal better

and faster than standard of care treatment alone in adolescents diagnosed with spondylolysis. Standard of care treatment includes back bracing, physical therapy, and rest from sports. Bone healing will be assessed using CT scans.

HAND AND UPPER EXTREMITY PROGRAM

Peter M. Waters, M.D., Donald S. Bae, M.D.

PROSPECTIVE STUDY OF THE TREATMENT FOR BRACHIAL PLEXUS BIRTH PALSY

This is a prospective, multi-center, center-randomized clinical trial of patients with brachial plexus birth palsy (BPBP). The primary aim of this trial is to determine the optimal age, three or six months, for microvascular repair of infants with BPBP and persistent upper extremity weakness. Secondary aims are: (1) to compare the functional outcome of patients who undergo microscopic repair alone versus reconstructive surgery alone, (2) to compare the functional outcome of patients who undergo microscopic repair and reconstructive surgery versus reconstructive surgery alone; and (3) to determine the natural history of neurologic recovery in patients with BPBP.

FUNCTIONAL OUTCOMES IN THE SURGICAL TREATMENT OF BRACHIAL PLEXUS BIRTH PALSY

The main objectives of this prospective study were to: (1) test the correlation of three functional upper extremity scoring systems, the Modified-Mallet, Toronto and Active Movement, with the AAOS' Pediatric Outcomes Data Collection Instrument (PODCI), and (2) validate these scales as predictors of outcome in children with BPBP. This study was partially motivated by the fact that the PODCI is more time-consuming to administer and score than the other three systems. Analyses revealed that all three scoring systems showed a positive correlation with PODCI sub-scores for upper extremity function, mobility and sports participation, thus establishing their clinical value in making treatment decisions and predicting patient outcomes.

SPORTS-RELATED INJURIES IN PATIENTS WITH BRACHIAL PLEXUS BIRTH PALSIES

The main objective of this prospective study was to assess the ability of children with BPBP to participate in sports and to quantify their rate of injury. The data suggest that a high percentage of children with BPBP do participate in sports at every level, despite lower than normal global and upper extremity function and comfort scores on the PODCI. The children who participated in sports sustained injuries at a similar rate to that seen in the general population.

BRACHIAL PLEXUS BIRTH PALSY: FACTORS THAT INFLUENCE PARENTAL DECISION MAKING FOR CLINICAL CARE

The purpose of this prospective cross-sectional study was to determine what influence the Internet has on decisions that parents make regarding their child's BPBP healthcare. The study revealed that a large percentage of parents use the Internet to research this rare condition, and although approximately half of these users will make healthcare decisions, in part, based on information obtained on the Internet, the majority feel more comfortable making their final decisions based on advice of healthcare providers.

ECONOMIC ANALYSIS OF BRACHIAL PLEXUS BIRTH PALSY

Part 1: The purpose of this economic analysis was to evaluate the benefits and costs of performing microsurgery at three versus six months of age in children with BPBP who have failed to regain biceps function by three months of age. The results suggest that it is unlikely that surgery at three months for rupture injuries will have a high enough success at preventing future operations to justify the cost. This finding is driven primarily by the fact that for non-avulsion injuries, eighty percent of BPBP patients experience spontaneous biceps recovery from four to six months of age. One major shortcoming of this study was the lack of preference based measures. Such measures incorporate patients' voices into treatment decisions. *Part 2:* A study was initiated to estimate the health-related quality of life impacts in BPBP. We used experts in the field of BPBP to determine if they could use two indices, the EuroQol (EQ-5D) and the Health Utilities Index Mark 2 (HUI2) to identify the attributes that best characterize the impacts of the health states associated with the management of this disease. While experts were able to quantify the deficit in quality of life experience by a child with an avulsion neurologic injury, they were unable to distinguish a child with a ruptured brachial plexus injury from a normal child using either instrument. These results show that the common practice of using experts in the field to value health states using utility measures needs further evaluation in the domain of brachial plexus birth palsies before being applied in economic analysis. *Part 3:* The final phase of this evaluation is to approach patients and families and ask them to assess how BPBP affects their activities of daily living. In this time of fiscal responsibility and awareness of the importance of patient satisfaction measures, there is a need to examine both costs and benefits of any management strategy. The EQ-5D will help to determine utility weights in the estimation of Quality Adjusted Life Years (QALYs) for economic analysis, which is an integral tool in incorporating patient's information into utilization analysis.

USE OF FREE VASCULARIZED FIBULAR GRAFT FOR CONGENITAL ULNAR PSEUDARTHROSIS

The purpose of this retrospective investigation was to review our institution's experience in treating congenital pseudarthrosis of the ulna with vascularized free fibular bone graft. Patients were followed for an average of 60 months, at which time all had achieved bony union with full wrist range of motion and a stable distal radioulnar joint. Revascularization of the distal ulna was achieved in patients nearing skeletal maturity and continued skeletal growth was seen in skeletally immature patients with concomitant epiphyseal transfer.

Publication: Bae DS, Waters PM, Sampson CE. Use of free vascularized fibular graft for congenital ulnar pseudarthrosis. J Pediatr Orthop 2005;25:755-62.

SURGICAL TREATMENT FOR TRIGGER FINGER IN CHILDREN

The objective of this retrospective case series is to assess the efficacy of a standardized surgical technique, consisting of A1 pulley release and resection of a single slip of the flexor

digitorum superficialis (FDS) tendon in the treatment of symptomatic trigger fingers in pediatric patients. This investigation is a continuation of earlier work which found that patients with an average post-surgical follow-up of three months, had recurrence of triggering that was much lower with this technique than a standard A1 pulley release. The average length of patient follow-up in this new study will be approximately five years.

SURGICAL TREATMENT FOR LONGITUDINAL EPIPHYSEAL BRACKETED PHYSES

The goal of this retrospective case series of skeletally immature patients who previously underwent surgical treatment of clinodactyly is to determine the: (1) efficacy of surgical treatment in the correction of clinodactyly, (2) risk of growth disturbance and/or physeal arrest following surgical treatment, (3) risk of recurrent deformity following surgical treatment, and (4) functional outcomes of and patient satisfaction with surgery.

OUTCOMES OF SURGICAL MANAGEMENT OF CHRONIC MONTEGGIA FRACTURES IN THE PEDIATRIC POPULATION

The primary objective of this retrospective case series is to assess the 2-10 year outcomes of contemporary surgical techniques in the management of chronic Monteggia lesions in children. Outcomes of treatment will be assessed by evaluating elbow range of motion, pain, functional status, and patient satisfaction.

TENODERMODESIS FOR CHRONIC MALLET FINGER DEFORMITY IN CHILDREN

The main goal of this retrospective case series is to evaluate the efficacy of tenodesis for the treatment of chronic mallet finger deformity in children. Patients who have previously undergone tenodesis as a part of their treatment for mallet finger deformity will be evaluated, with specific attention to correction of the primary deformity, avoidance of secondary deformity, return of digital motion and hand function, and avoidance of additional non-operative or surgical treatment.

ARTHROSCOPIC TREATMENT OF PARTIAL SCAPHOLUNATE LIGAMENT TEARS IN PEDIATRIC AND ADOLESCENT PATIENTS WITH CHRONIC WRIST PAIN

The primary objective of this retrospective case series was to assess the outcome of patients who presented with persistent wrist pain and instability, had documented scapholunate ligament injury and failed at least six months of non-operative treatment; and then were treated arthroscopically. The data collected suggest that long term improvement is achieved after debridement of the tears and arthroscopic treatment of other associated injuries.

ADOLESCENT AND YOUNG ADULT HIP PROGRAM

Michael B. Millis, M.D., Young-Jo Kim, M.D., Ph.D.

CLINICAL OUTCOMES OF BERNESE PERIACETABULAR OSTECTOMY IN HIP DYSPLASIA

The major goal of this prospective data collection effort is to develop a comprehensive database with clinical, radiographic and outcome data for patients who undergo periacetabular osteotomy (PAO) for developmental dysplasia of the hip. A retrospective review of the data was conducted to: (1) assess long-term efficacy of this joint-preserving surgery, and (2) develop a model to predict probability of failure. An analysis of patients with an average follow-up of nine years has resulted in identification of three independent predictors of failure: age, joint congruency, and minimum remaining joint space.

CLINICAL OUTCOMES OF SURGICAL DISLOCATION OF THE HIP

The major goal of this prospective data collection effort is to develop a comprehensive database with clinical, radiographic and outcome data for patients who undergo surgical dislocation of the hip. A retrospective review of the data was conducted to: (1) assess long-term efficacy of this joint-preserving surgery, (2) characterize complications associated with this procedure, and (3) evaluate factors that may lead to failure. An analysis of patients with an average follow-up of two years shows that this is a safe, effective procedure for a variety of intra-articular hip problems ranging from post-slip deformity to cartilaginous exostoses. Failure risks are increased with older age and pre-existing chondral damage such as labral tears and/or chondral flaps.

ASSESSMENT OF OSTEOARTHRITIS IN HIP WITH FEMOROACETABULAR IMPINGEMENT USING DELAYED GADOLINIUM ENHANCED MRI OF CARTILAGE

The main objective of this retrospective case series was to determine the feasibility of assessing early osteoarthritis in hips with femoroacetabular impingement using delayed Gadolinium Enhanced MRI of Cartilage (dGEMRIC). Preliminary results show that, similar to dysplastic hips, dGEMRIC correlates with pain and lateral center-edge angle (LCE) and is a useful tool for detecting early osteoarthritic changes in hips with femoroacetabular impingement.