Joint Implant Surgery & Research Foundation

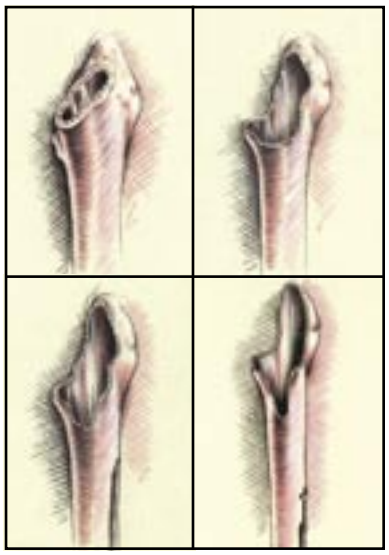
February 2005

JISRF Update

Difficult Hip Revision Surgery, Can It Be Easier?

Introduction

By Timothy McTighe, Editor



THA has become increasingly more sophisticated and demanding as we encounter more difficult and unusual situations.

Since 1971, by the pioneering efforts of its Founder Dr. Charles O. Bechtol, JISRF has brought to the orthopaedic community's attention new techniques, product and research tools in the effort to advance the practice and outcomes of total joint surgery[21]. This edition will highlight three new technologies that we believe can provide the community orthopaedic surgeon new approaches to making difficult hip revision surgery easier, more cost effective and provide for practical clinical outcomes.

Over the past thirty years, total hip revision surgery has become increasingly more sophisticated and demanding as we encounter more difficult and unusual situations[15,20]. The use of autografts, allografts, modular and custom implants place a high demand on both the surgeon and the surgical team. The demands on experienced OR personnel place a higher cost on the procedure, as does the increased surgical time to perform hip replacement surgery. As a result, the Community Hospital sees no financial reward to offering this treatment modality to its local patients. This is becoming a significant problem to the local community requiring patients to travel greater distance placing more burdens on the family and the family's budget.

Understandably, cases involving difficult hip replacement do not lend themselves to scientific review with statistical analysis. They do, however, give an opportunity to discuss experiences with certain interesting and unusual problems[6,7,20].

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Joint Implant Surgery and Research Foundation is a non-profit scientific and educational organization founded in 1971 by professor Charles O. Bechtol, M.D.

The foundation over its past 30 years has conducted CME activities for both surgeons and nurses while sponsoring clinical /surgical study groups, including basic science projects that have led to the development and marketing of significant Total Joint Replacement Implants.

Modular Revision Stems

This issue's Feature Article highlights the use of modular multi-component femoral stems in revision hip arthroplasty.

Modularity - does it seem confusing to you?

Modular total hip stems are not new but what is new is the idea of a comprehensive modular stem system that allows the surgeon to select the best possible design features intra-operatively with a simple reproducible instrumentation system. Remember it is important to understand the specific design features and techniques for each modular stem design and not to lump all designs into one simple category "Modular Stems". In fact, modular sites, designs, features, material, fabrication and quality can be quite different in nature and sophistication[16].

There are many competitive revision modular stems currently on the market. Some have proximal modular features, and some mid-stem modularity. Most designs that featured distal modularity have been discontinued due to either poor performance or lack of clinical/ surgical need.

Distal sleeve.

For additional information on cementless modular stems you can review May, 2002 JISRF Update Newsletter.

Also covered in this issue is a new approach to surgical retraction featuring a table-mounted system called Omni-Access™ from Omni-Tract Surgical.

Surgical exposure is always a challenge with revision surgery. This table-mounted device provides excellent exposure with features that place less traction on the skin edges, minimize bleeding and reduce the need for additional surgical assistants.

A new way of generating hard post-operative outcome data in a cost affordable manner is the IDEEA® LifeGait™ System (Intelligent Device for Energy Expenditure & Activity).

FEATURE ARTICLE

Modular Stems for Revision THA

By H. Del Schutte, Jr., M.D., Harry A. Demos, M.D., Neil C. Romero, M.D., Timothy McTighe, Dr. H.S. (hc)

Introduction

Revision hip arthroplasty has become an increasingly common surgical procedure. Approximately 100,000 joint revisions are done per year in the United States and reports indicate an increase of 11-13% in 2004[10]. In comparison to primary THA revisions are associated with a markedly increased technical difficulty, increased complication rate and cost. The primary challenge in revision hip arthroplasty is stable implant fixation in the face of significant bone loss. As this bone loss is most common in the proximal femur, the most widely used implants are those which obtain fixation in the distal diaphyseal bone. Traditionally, the most commonly used revision stems are distally fixed non-modular implants. The ability to adjust version, offset and length is limited once distal fixation is achieved. These constructs have association with markedly higher dislocation rates when compared to indexed THA. Primary rates running from 1.4% to 4.2% with a mean 3.1%. Revision rates range 3.2-10.5% with a mean of 9.4%[14]. Recently there has been an increase in the use of distally fixed proximal modular stems in an attempt to decrease the implant and joint instability and offset problems occurring during revision hip arthroplasty.

The goals of revision surgery remain the same as primary arthroplasty: reduction of pain; equalization of leg length; restoration of movement; creation of joint and implant stability. However, to accomplish the reconstruction successfully, often requires the use of autografts, allografts and modular implants[8,15].

The most common cause of proximal bone loss is due to osteolysis and aseptic loosening, resulting in a variety of femoral deficiencies that makes revision surgery more difficult[3,15].

The AAOS and a number of authors have defined and classified femoral defects[1,8]. Some of these classification systems are quite complex and require the need of a reference chart. Mattingly et. al., presented a modified AAOS classification system in a Scientific Exhibit "Revising The Deficient Proximal Femur" at the AAOS 1991 Annual Meeting. This system was helpful but still quite comprehensive. We prefer to use a simpler classification[11] that has proven to be helpful for selection of specific implant design features.

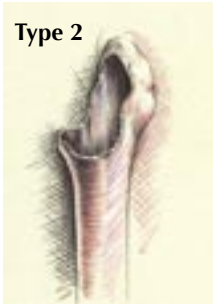
Assessment of Bone Loss

Type 1 - Minor Bone Loss
- The metaphysis is slightly expanded, but intact.
- There is minor calcar loss
- There is slight cavitary expansion
- The diaphysis is intact

Type 2 - Significant Bone Loss
- The metaphysis is comprised.
- Calcar is gone
- There is cavitary expansion
- Proximal bone is thin and incapable of structural support
- The diaphysis is intact

Type 3 - Massive Bone Loss
- Proximal cavitary and segmental bone loss extending to the diaphysis.
- Metaphysis and part of the diaphysis are deficient.
- The metaphysis offers no rotational stability.
- There is massive cavitary expansion.
- Implant stability is dependent on distal diaphyseal fixation.

Type 4 - Extreme Bone Loss
- Extensive proximal circumferential segmental bone loss
- Extensive cavitary diaphyseal loss
- Extensive ectasia of the diaphysis.
- Compromised cortical bone requiring strut grafts.
- Segmental defects requiring strut gratf and wiring
- Cavitary defects requiring impaction grafts.

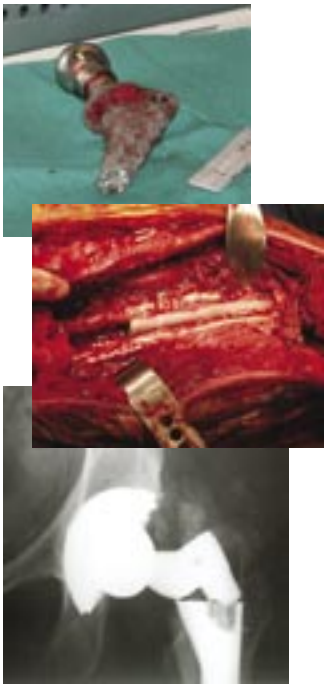


While revision surgery is technically demanding, this paper will demonstrate that it is possible to achieve short term success in treating revision hip surgery with a new comprehensive modular revision cementless stem system.

Area of Concern

Fatigue Strength

All devices are subject to fatigue failure especially with the increased patient activity we are seeing today. There are reports of device failure regardless of material, and regardless of design style (monoblock, modular). Recent reports of failures of total hip stems have led to more vigorous testing and the development of implants with improved material properties. In addition stems have been designed with greater ability for bony fixation at all levels of the stem. It is anticipated that all stem designs which allow for better fixation have the potential to be less susceptible to late failure. Recognizing design and material limits is part of the surgeon's responsibility in choosing the appropriate implant[16].



Fx. c.c. cemented

Fx. Bridge™ Titanium Cemented

Fx. c.c. cementless

The issues of fatigue, fretting and corrosion are areas that we are all concerned with and need to know how our individual modular devices stack up. It is not possible for community based orthopaedic surgeons to know or be familiar with all the current standards for material testing but we do have a responsibility to demand and review from device manufactures appropriate material test on the devices we are using especially new materials and designs.

Patient activity is placing higher demands than ever before on total joint reconstruction and revision surgery is often the reality especially when one does not understand or appreciate the limits of design and /or material of the device that is selected.

It was not that long ago that we faced problems with modular acetabular cups, concern over corrosion at head/neck tapers and lysis generated by particulate debris due to fretting abrasion wear[4,5]. Orthopaedic industry has made significant advances in high quality manufacturing and implant design that have resulted in increased product offerings.

Examples of increased patient activity.

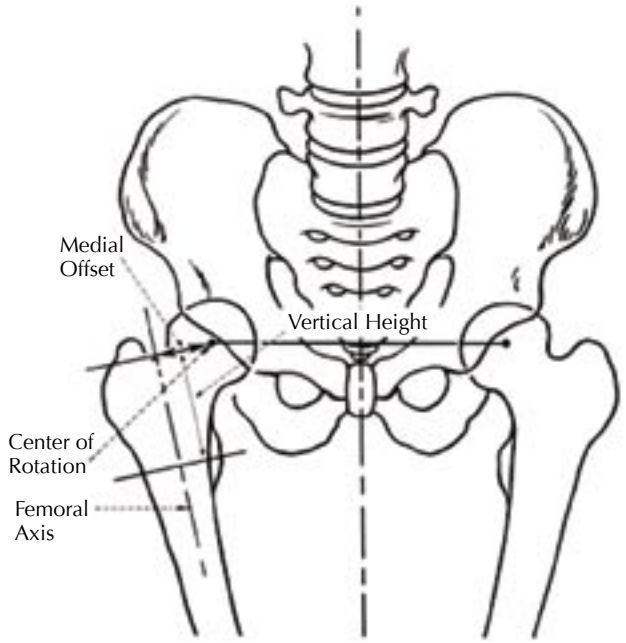
There are a number of methods available to a manufacturer to increase fatigue strength and reduce fretting wear. However, no individual design, material, or process offers absolute guarantees with regard to mechanical failure given the increased popularity of high-impact activities in today's lifestyles.

The modular junction of the Restoration® Modular Stem is designed to transfer loads over a large surface. Additionally, the manufacturer utilizes a proprietary shot peening process which enhances the taper junction to improve fatigue and long-term performance.

Restoring Hip Mechanics

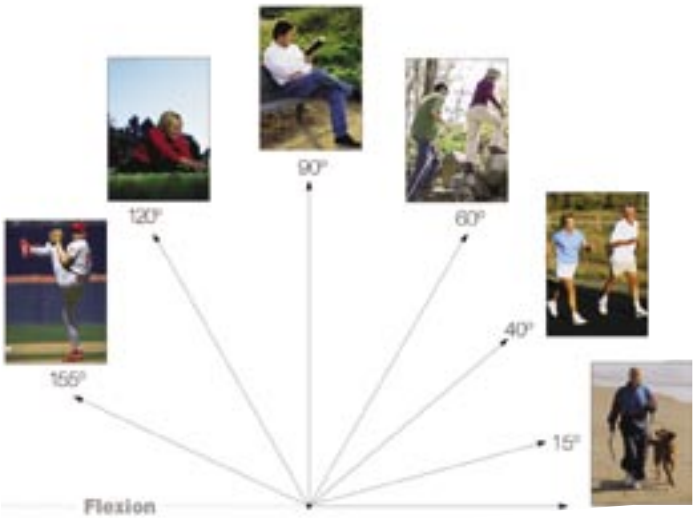
Restoration of hip joint mechanics is critical to a successful outcome for all total hip reconstruction[18]. Correction of femoral head offset affects the joint reaction line and helps restore mechanical balance between adductor forces[7,12]. If the offset is too short it will result in increased resultant forces across the hip joint, and possibly increase limp[7]. Offset too great will increase torsional and bending forces on the femoral implant.

Vertical height too short can jeopardize joint stability and if too long can result in nerve palsy and patient complaints. Incorrect version angles can impact range of motion resulting in implant impingement, joint dislocation, and increased generation of particulate debris.

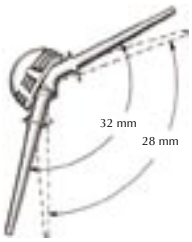


Range of Motion

Activities



Two factors that can affect range of motion are component positioning and component geometry[9,13]. Head diameter, neck shape and skirts on femoral heads can all affect hip range of motion[13]. Although physiological range of motion varies for each patient an average of 114° of flexion is required for sitting. There is no question that certain activities require a greater degree of motion.



Major Problems

Two major problems in revision hip surgery are joint stability and correction of leg length. According to Dr. Hugh U. Cameron the most significant medical/legal concern in THA is leg length discrepancies. Estimating dislocation rates of both 2% and 10% there would be a corresponding 6 to 30 thousand dislocated hips each year. Subsequently total cost of dislocations in the U.S. would be $64.5[22] to $322.5 million respectively.

Leg length.


Hip Dislocation.

Implant Selection

Immediate implant stability is necessary for cementless revision arthroplasty to work. Often to achieve implant stability the metaphysis must be bypassed and fixation achieved in the diaphysis. It has been previously reported that a constant proportional relationship is not present between the shape and size of the metaphysis and diaphysis. The revision situation results in additional alterations in the normal bony architecture, making fit and fill more difficult to achieve.

The Restoration® Modular Stem system allows for independent selection of proximal bodies and distal stem styles and lengths. The mixing and matching of the modular components provide significant versatility in treating femoral deficiencies. The proximal body is attached by means of a taper lock that has received proprietary processing (shot peening) yielding higher fatigue, fretting and torsion results.

This report will focus on our experience using the cone-shaped proximal bodies of the R/M Cone, RT3 and Link MP™.

Fifty Restoration® Stems were used for revision of indexed primary stems, secondary revision stems, and infections. A variety of bone dificiences were encountered from minor bone loss (type 1) to extreme (type 4) requiring both impaction and strut grafts.

Of the fifty, thirty-five stems were the original T3 design, fifteeen stems were the new Restoration® Modular cone, and twenty-three Link MP stems.

Restoration® Modular Cone

Link MP stem

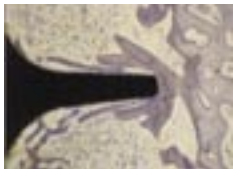
Distal Stems

Distal stems of the Restoration® Modular are available in three different styles including fluted, plasma coated, and conical straight taper stem. All stems are available in a variety of lengths and styles (straight and bowed). Our experience is with the conical stem.

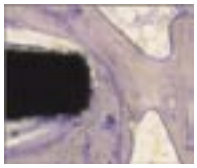
The fluted distal stem of the Restoration Modular is designed from the successful stem geometry of the Wagner stem that has demonstrated excellent bone adaptation as shown to the right in this retreived specimen.

The versatility of this system allows interchangeability of the largest proximal body with the smallest stem. Although this is an extreme example this feature provides for dealing with femoral proximal/ distal mismatch[20].

Cross section, distal region



Flute, 11x magnification



Flute, 30x magnification

Retrieval 5.5 months after implantation, 65 year old, 85kg patient.

R.K. Schenk, U. Wehrli; On the reaction of the bone to a cementless SL femur revision prosthesis; Orthopade (1989) 18; 454-462

Sizing Versatility

Examples of Difficult Cases

Infected cemented stem.

Antibiotic cement spacer.

Revision modular stem.

Infected hip revision. Antibiotic cement spacer.

Revision modular stem with strut grafts.

Initial post-op.

Two months post-op.

Loose cemented stem.

Revision restoration conical cone one year post-op.

Impaction graph three years post-op.

Results

- 99-02 23 Link MP
  - 1 stem fracture
  - 1 dislocation
  - 0 clinically observable subsidence or aseptic loosing
- 01-Current 50 restorations
  - 01-03 35 RT3
  - 04-Current 15 Restoration Modular
- 2 patients deceased
- 3 patients lost to follow-up
- 0 dislocation
- 0 fractures
- 0 revisions
- No measurable subsidence

Long-term data is necessary to clearly demonstrate the viability of modular revision systems. However, recent improvements to mechanical properties of the taper along with proven stem design features should aid the surgeon in restoring normal mechanics to the reconstructed hip.

Predictions and Concerns

- Modularity is here to stay
- Increased Patient Activity & BMI Influences Outcomes & Device Failure
  1. High Impact Yield Failure
  2. Long Term Fatigue Failure
- Increased Device Malposition due to Limited Exposure
- Increased Medical/Legal Exposure

Final Comments

- All devices are subject to failure.
- Recognize design and material limits and do not over indicate,
- Warn your patients that device failure is directly linked to activity and BMI.
- Recognize required technique for specific modular designs and do not attempted to change surgical technique and device technique at the same time.
- Revisions are always with us – therefore select devices that take retrievability into account.

Surgeon Highlight

President Australian Orhopaedic Association

2004

1968

Dr. John M. Harrison

B.Sc.(Med) MBBS FRCS FRACS FAOrthoA FAMA FACSP

Medical politics has always been a special interest for Dr Harrison despite a busy orthopaedic practice. Before taking up a years term of office as National President of Australian Orthopaedics in October 2004,

Dr Harrison completed a three months tour as Honorary Manager and Doctor with the Australian Men's Water Polo team attending pre Olympic competitions in The United States and Europe. Being a past National Australian Water Polo goalie selected for the 1968 Mexico Olympics, attending the Athens Olympiad as an honorary official was a challenging experience from a different perspective.

Education
University of Sydney 1961 – 1969

Residency
JRMO Royal North Shore Hospital Sydney 1970
Mona vale District Hospital Sydney 1971
SHO St Bartholomews Hospital London 1972
JSR St Bartholomews Hospital London 1972-73
ASR St Bartholomews Hospital London 1973
OR Royal North Shore Hospital Sydney 1974
OR St George Hospital & R.A.H.C. Sydney 1975
SOR Prince of Wales Hospital Sydney 1976

Hospital appointments
Parramatta Hospital 1976-81
Lottie Stewart Hopsital 1977
The Hills Hospital 1978-
Westmead Hospital 1978-84 / 89-94
Auburn Hospital 1981-84/89-93

Other appointments
Honorary Orthopaedic Surgeon:
NSW water polo 1978-83
Cumberland Cricket Association 1983-4
Member Board of Advice Hills Private Hospital 1992-7
Parramatta Rugby Union Club 1986-93
Hills district Rugby League Football Club 1992-5
Australian Women's Water Polo Side 1994-
Kellyville District Rugby League Football Club 1996-9
Austalian Mens Water polo Team (Manager) 2003-

Currently
Member
Co-ordinating Committee WorkCover NSW
Medical Liasison Committee AMA & Law Society NSW

National Chairman Australian Society of Orthopaedic Surgeons
President Australian Orthopaedic Association

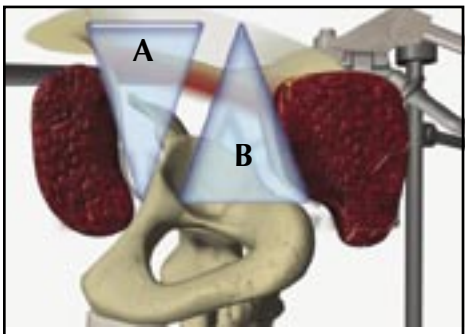
Society Memberships:
Australian Orthopaedic Association
Australian Society Orthopaedic Surgeons
Australian Association of Surgeons
Australian Orthopaedic Foot and Ankle Society
Arthroplasty Society of Australia
Royal Australasian College of Surgeons
Australasian College of Sports Physicians
Sports Medicine of Australia
Australian Medical Association
American Academy of Orthopaedic Surgeons
Medico-Legal Society of NSW
Australian Academy of Medicine and Surgery
General Medical Council - London

A Table-Mounted Retraction System is Setting a New Standard For Hip Exposure the OmniAccess™ Hip Retractor System

By Hugh U. Cameron, M.B., C.H.B., Timothy McTighe, Dr. H.S. (hc)

The objective of retraction in surgery is to provide visualization. To do this, the tissues are pulled apart.

In joint replacement surgery, Homan retractors are commonly used. The point is fixed to a bony prominence and the assistant pulls on the handle. Because they are fixed to bone close to the area to be visualized, e.g. the acetabulum, the hole or viewing port produced is shaped like a truncated wedge. This results in greater retraction on the skin and superficial tissues than on the deep tissues so that the skin incision is much longer than the inner incision.



A depicts surface retraction of a hand-held instrument (Homan). **B** shows the toe-in feature for deep retraction of the OmniAccess Hip Retractor System that enables better exposure with less tissue trauma.

Right angle retractors held by the assistant are safer than Homans as they do not have a sharp tip and thus potential damage to nerves and vessels is reduced. They can be angled to produce as much retraction at the object of visualization as they do at the surface and, therefore, they produce a parallel-sided hole. They are, however, very tiring to hold. As with all hand-held retractors, movement inevitably occurs as the assistant becomes tired or distracted and the position or visualization is lost requiring frequent retractor reinsertion.

Traditional handheld retractors (Homans, Right angle, deep blade, bone hook)

The advantage of a table-mounted instrument is that both the system and the patient are fixed in place. Once inserted, position loss is largely eliminated and the assistant's hands are free to help with other parts of the operation such as suction, etc.

The OmniAccess Hip Retractor System allows for fixation of traditional Homans, bone hooks and also right-angled retractors. One significant feature is the ability to toe-in the distal portion of the right angle blade. This produces more exposure at the depth of the wound, thus producing an inverted truncated cone so that the tension on the skin and superficial structures is lessened and, therefore, the incision does not have to be as large.

First assistant is suctioning and there is no need for a second assistant.

This system is of considerable value, especially in hip revision surgery enabling this to be done comfortably and expeditiously with only one assistant. The system works well with all surgical approaches and provides for constant, simple, reproducible exposure and has helped in reducing operating time for complex cases.

We want to acknowledge and thank Drs. Kris and John Keggi who brought this system to our attention and have also had success in using this in their MSA™ (Muscle Sparing Approach) as shown in the following photo.

Keggi MSA™ anterior surgical approach.

"Mobile Gait Analysis" A New Tool for Post–Op THA Evaluation

By Kevin Lester, M.D., Ming Sun, Ph.D., Timothy McTighe, Dr. H.S. (hc)

The value of sophisticated, video-based gait analysis is well established.

However, the cost of establishing a gait clinic is very high (+$250,000). These systems also require highly trained and dedicated personnel. As a result, the routine use of gait analysis in clinical practice has been very limited.

In addition, though in-patient gait labs offer highly sophisticated motion analysis, the lab environment does not mirror the patient's actual living conditions, or motion requirements. It can be difficult to determine the relationship between video kinematic data and the level of a patient's disability in every day living.

The need and potential clinical value of an inexpensive, accurate, easy to use gait analysis system has been repeatedly cited in the medical literature. In particular, the value of an ambulatory system that could acquire gait data from either defined protocols, or actual living conditions, and provide automatic quantitative data analysis.

Years of research have resulted in the development and clinical use of a mobile gait analysis system that can be used in actual living conditions. The IDEEA™ LifeGait System (Intelligent Device for Energy Expenditure & Activity) provides accurate measurement of physical activity, functional capacity and gait analysis.

For any device to be used by patients successfully it must be user friendly. The IDEEA® is a small portable unit the size of an IPOD® and does not hinder any physical lifestyle activity. Once attached to the patient it provides continuous recording from a few minutes to several days. Utilizing pre-determined protocols, gait studies can be performed; in addition, data can be recorded under natural work or living conditions.

More than 45 types of activity can be measured.

Gait cycle measured by the sensor from right foot.

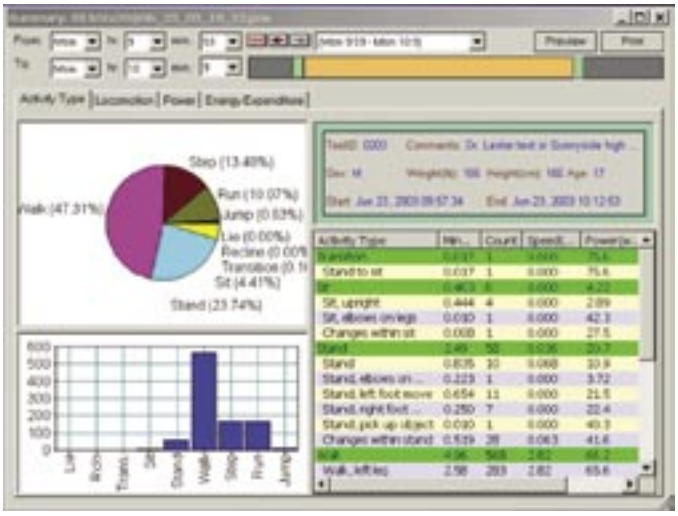
Data Reporting

Reports can be generated immediately in the form of tables, charts, animation and histograms.

Validation of accuracy studies has been done by a number of well-known and respected centers:

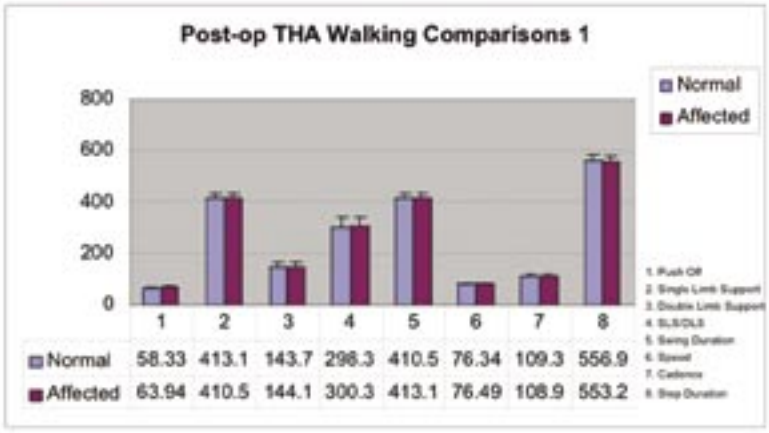
- Locomotion study by Columbia University (99%)
- Energy Expenditure by Columbia University & Vanderbilt University (96%)

The following chart demonstrates examples of our senior authors example of using this device for THA patients. Demonstrating that the posterior approach for THA results in virtually no limp.

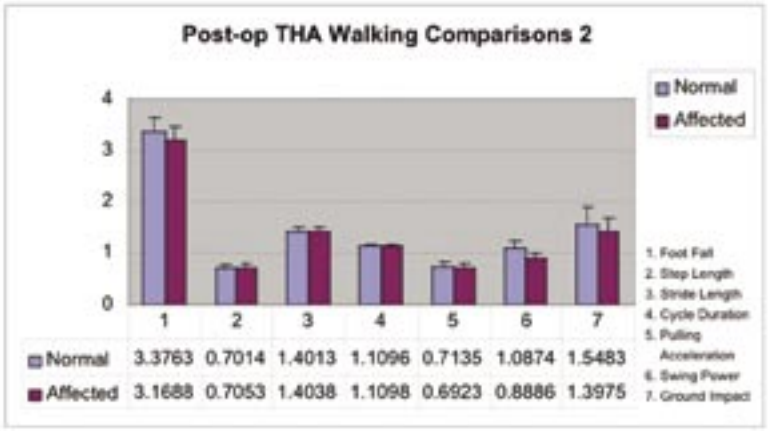


Gait Analysis Using IDEEA System

The following data are group average of 8 patients who had THA surgery.



Gait Analysis Using IDEEA System



In summary we feel the IDEEA LifeGait System provides useful cost effective data for pre and post assessment of total joint patients. In addition other applications aid in the evaluation of workers compensation, balance assessment, and fall risk in patients natural living environment. Measurement of post trauma impairment along with physical therapy monitoring, assessment of orthotic and prosthetic devices and research uses specifically outcome assessment of new surgical procedures or rehabilitation methodologies.

We continue to use the device and recommend that all surgeons interested in objective outcome analysis should consider this technology for use in their own practice.

Kevin Lester, M.D.

Commentary

The article by Schutte and colleagues suggests an approach to the use of modular components for the revision of the femoral component in THA revision. Since the advent of the SROM prosthesis it has been clear that modular approaches can be useful to successfully address implant stability, the restoration of joint kinematics and joint stability in hip arthroplasty. These aspects of arthroplasty are substantially more complex in the Revision situation, and modularity will be an important mechanism to address these same issues in increasingly complex revisions. The authors point out a number of features of modular revision systems that must be addressed by the manufacturer and implanting surgeon, and provide us with their early experience using the restoration modular system and Link MP System. The experience is too early to draw conclusions from, but only to suggest that the features of the systems allowed the surgeons to address the circumstances they faced in an effective manner. Longer term data with cases classified according to the degree of bone loss (using a classification system such as they have suggested) will allow us to draw conclusions as to the long term benefits of this particular system.

The article on the OmniAccess hip retractor provides us with information regarding a useful surgical tool. Retractor systems are now becoming available and necessary in operating environments that require increasing predictability. This system appears worthy of careful evaluation and will likely prove helpful for many surgeons performing hip surgery.

The IDEEA device is a novel device offered to allow the practicing surgeon to perform increasingly sophisticated functional analysis of the patients undergoing joint replacement surgery. Many total joint surgeons believe it is important to document improved performance of their patients, and tools to measure pre and postoperative performance are needed. If this system can continue to demonstrate accuracy of measurement compared to more expensive approaches, it will become a useful tool in the clinical practice of Total Joint Replacement.

Bernard N Stulberg MD
Director: Center for Joint Reconstruction; Cleveland Orthopaedic and Spine Hospital;
Cleveland Clinic Health System
Cleveland Ohio

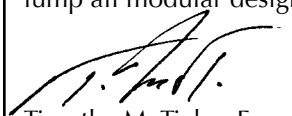
JISRF Position

For over thirty years JISRF has sponsored educational activities, newsletters for surgeons and patients, as well as conducting clinical/surgical study groups. The tradition as established so many years ago, by Professor Charles O. Bechtol, M.D., is not to endorse any one individual product/technology/technique but to expose new mothodologies in a fashion that would raise the level of awareness and debate over a particular issue.

Over the past few years we have seen clinical outcomes for most devices demonstrate good to excellent results. It is difficult to say one device is better than another in light of all the considerable variables that must be taken into account. This issue is highlighting three new technologies that we feel have some significant features that might benefit the orthopaedic community. There are sufficient short-term results that warrant exposure in the "UpDate" and we encourage the orthopaedic community to review these devices.

All of the above issues require further investigation and consideration. Additional refinements and modifications will certainly be made, however these technologies represent an exciting direction for the field of reconstructive surgery. JISRF will do its best to keep you informed on the progress and performance of these technologies.

Remember, when it comes to modular implants it is important to understand and appreciate the specific design features and required techniques for that design. Do not lump all modular designs into one simple category "Modular Stems."



Timothy McTighe, Executive Director, JISRF

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