# Reconstructive REVIEW

OFFICIAL JOURNAL OF THE



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### Greenbrier Resort



**Since 1948, the Greenbrier Clinic** has been recognized as an industry leader in executive health and wellness through utilizing advanced diagnostics in the early diagnosis, prevention and treatment of disease. Building upon that history of medical excellence, Jim Justice, Chairman and owner of the Greenbrier Resort, has announced the creation of the Greenbrier Medical Institute. The institute's 1<sup>st</sup> phase is projected to cost about \$250 million, employ more than 500 people and include 3 buildings.

This phase will include an expansion of our world renowned executive health and wellness practice, The Greenbrier Clinic, which will be bolstered by a world-class sports medicine program, including an orthopedic surgery center and athletic performance/rehabilitation facility, all led by the Founder of the American Sports Medicine Institute, Dr. Jim Andrews and Chair of Cleveland Clinic Innovations, Thomas Graham. Rounding out the Institute's services will be a first-in-class plastic and cosmetic surgery and Lifestyle Enhancement Academy, helping people look and feel their best. Physicians, universities, research foundations, medical journals and other healthcare industry leaders, all of whom are on the cutting edge of medical technology, research and care, have committed to join the project and establish an international research and education destination or "think tank" to stimulate research, drive innovation, force change and redefine how the world approaches health, wellness and longevity.

The Institute's facility, designed by Willie Stokes, will feature Georgian architecture similar to

the resort's façade, a replica of the Springhouse, the site of the famous sulphur springs and special guests suites for patients and their families. Jack Diamond, President and CEO, and Mark Krohn, COO, are leading the development of this exciting project and are actively looking for other physicians and medical thought leaders to be involved.

For more information, please contact:

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### **Reconstructive Review**

A Journal Published by the Joint Implant Surgery & Research Foundation



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Submit manuscripts and correspondence electronically to Executive Director, at email: tmct@jisrf.org

Manuscript submissions are accepted with the following requirements:

- Manuscript must be submitted as Word or PDF files
- Any images files should be included as TIFF, JPG, or EPS at a minimum of 300 dpi.
- Any questions regarding these requirements please send to media@jisrf.org

There is no subscription charge for receipt of this publication. This is done as a service keeping with the overall mission of JISRF.

#### Mission Statement:

The specific and primary purposes are to operate for scientific purposes by conducting medical research of improvements in medical and surgical methods and materials for preserving and restoring the functions of the human body joints and associated structures which are threatened or impaired by defects, lesions or diseases.

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### JISRF Announcements



**Timothy McTighe, Dr. HS (hc)** Executive Director, JISRF & Editor-in-Chief Reconstructive Review

ctober 2011 we published our first full edition of our new journal "Reconstructive Review". In 2012 we published two ICJR supplements (April & October) and one full journal in August.

As we move into 2013 we are pleased to publish our third full journal while continuing to set up our internal processes for moving towards quarterly publications. We continue to look forward to publishing select supplements of ICJR CME Meetings.

### **JISRF Mission Statement**

The specific and primary endeavors are to operate for scientific purposes by conducting medical research of potential improvements in medical surgical methods and materials for preserving and restoring the functions of the human body joints and associated structures which are threatened or impaired by defects, lesions or diseases.

This Journal as all activities conducted by JISRF are available to all interested surgeons, scientists and educators. Our focus is on new cutting edge technologies, science – all with the intent to raise the level of discussion and discovery. Please become a part of this endeavor, we look forward to your interest and participation.

### **New Endeavor**

#### JISRF Investigational Review Board

JISRF's Board of Directors have approved the formation of an Investigational Review Board (IRB).

JISRF has a long rich history of conducting clinical/surgical research projects. There has been considerable interest in JISRF establishing a formal IRB Committee. The specific purpose of this IRB Committee is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a research study. JISRF's IRB Committee will attempt to ensure protection of subjects by reviewing research protocols and related materials. IRB protocol review assesses the ethics of the research and its methods, promotes fully informed and voluntary participation by prospective subjects capable of making such choices and seeks to maximize the safety of subjects.

JISRF has lectured and published on ethics and full disclosure since 1993. The Board sees the IRB Committee as a next logical step in interdisciplinary research and education while protecting the individual patients rights on full disclosure with regard to decision making of new technologies and potential conflict of interest in an ever changing health care environment.

Research grants, charitable contributions and revenue from our general fund support the IRB's work.

#### Disclosure

As part of fulfilling his or her responsibilities, and to assist the JISRF's IRB Committee in avoiding or managing Conflicts of Interest, each member must disclose:

- All outside activities and relationships that are relevant to an IRB Committee Member, whether compensated or not and include but not limited to activities and relationships that result in outside income, royalties and equity holdings. All Investigators must disclose:

- a. Any Significant Financial Interests he or she has in any project that is being proposed to an external funder (whether the investigator is or is not the proposed PI of that project, and whether JISRF will be the primary institution or involved under a subcontract or other arrangement),
- b. Any Significant Financial Interests he or she has in an externally funded project to which it is being proposed that the Investigator be added, and
- c. Any Significant Financial Interest that the Investigator proposes to acquire during the course of an externally funded project.
- d. Such disclosures must be made when a project is proposed to a funder, and thereafter annually and whenever a new Outside Activity or Relationship, or Financial Interest arises.

This policy confirms JISRF's commitment to the basic values of openness, academic and scholarly integrity, integrity of business policy and procedure, independence, and safe and ethical research, as well as to its tradition and expectation that all will conduct their relationships with JISRF with candor and integrity. To ensure the integrity of all institutional activities, including review and conduct of research (including research involving human subjects), and the associated fiscal, contractual and procurement transactions, regardless of the source of support, JISRF has elected to apply the same Conflicts of Interest policy to all its activities.

Timothy McTighe, Dr. HS (hc) Executive Director, JISRF

# JISRF Founder



### Charles Bechtol, MD

was internationally known in the fields of biomechanics and orthopedic surgery. His engineering and biomechanical research resulted in the development of numerous joint replacement implants and internal fracture fixation devices – instruments that are familiar to orthopedic surgeons the world over. His innovations included shoulder and knee prostheses, the Bechtol Total Hip system, the Bechtol "fluted" bone screw, and the Bechtol "continuous strength" bone plate.

Visit www.jisrf.org for more information...

## Strategic Alliance Announcement



### Joint Implant Surgery & Research Foundation

is Lleased to Announce a Strategic Alliance with the



Donaldson Arthritis Research Foundation

DARF, founded in 2005 by Dr. Thomas K. Donaldson, has a focus on outcome studies and basic science with major emphasis on implant retrievals. His ongoing collaboration with Ian Clarke, PhD provides a synergy between the laboratory and clinical surgical science. Both men are Board Members of JISRF and have a significant working relationship with its Executive Director Timothy McTighe Dr. HS (hc).



Ian Clarke, PhD & Thomas K. Donaldson, MD

JISRF, founded in 1971, has had significant experience with continuing medical education, product development, and clinical surgical evaluation of total joint implant devices.

The long term relationships JISRF has with total joint surgeons world wide and the experience of its Co-Directors and research evaluation equipment of the DARF Retrieval Center make for a strong long-term relationship.

Together both groups will provide unprecedented analysis of your Retrievals.



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### Instructions to Authors

### **Submission of Articles**

The Reconstructive Review uses a web-based service requiring authors to submit their manuscripts electronically. Authors register at www. JISRF.org.

### Please use the following format:

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- 2. Informed Consent: Any manuscript dealing with human subjects must include a statement that proper disclosure was given and patient consent received.
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- 5. Structure of manuscript:
  - Structured abstract Note: do not include abstract with case reports
  - Introduction
  - Materials and Methods
  - Results
  - Discussion
- 6. Structure of endnotes (please refer to the following website): http://medlib.bu.edu/facts/ faq2.cfm/content/citationsama.cfm

We welcome letters to the editor and acceptance is at the sole discretion of the Editor.

### **Journal Articles**

- Original Articles
- Clinical/Surgical
- Basic Science
- Case Reports
- Historical Reviews
- Surveys
- Commentary
- Letters to the Editor

The emphasis for these subjects are to address real life orthopaedics in a timely fashion and to encourage the participation from a broad range of professionals in the orthopaedic health care field.

We will strive to be responsible and reactive to the needs expressed to our editors and all members of JISRF. We anticipate our format will evolve as we move forward and gain more experience with this activity. Your opinion is a critical step to our motivation and overall success so don't hesitate to communicate to us.

### JISRF Reconstructive Review Specifications

The Reconstructive Review is currently constructed using InDesign running on a Mac. The document is published on the web, available for download as a PDF at jisrf.org, and printed in limited quantities.

- Trim Size: 8.5" x 11"
- Live Area: 7.25" x 9.25"
- No Bleeds

### Ad Specifications

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### The X-10: A Revolution in Knee Rehabilitation

David K. Halley, MD<sup>†</sup>, Paul Ewing, BME, MBA<sup>\*</sup>

#### Abstract:

The X-10 is an innovative knee rehabilitation machine that uses *Variable Pressure* technique to move the knee below the patient's pain threshold, within days rather than weeks, focusing on terminal flexion and extension. Pumping fluid away from the knee during the first two stages of fibrosis prevents the ultimate formation of scar tissue.



More than 500,000 patients underwent total knee arthroplasty (TKA) in 2012 in the United States alone, a number that is expected to exceed 3,480,000 by the year 2030.<sup>14</sup> The rehabilitation process for TKA patients is extensive, costly, and does not always yield optimal results. Many patients struggle to regain full mobility following TKA because stiffness in the knee joint can quickly progress to scar tissue in a short period of time. If this process is not prevented, scar tissue may impede flexibility in the future. Lack of full range of motion not only affects gait and mobility, but can also lead to future back and hip pain. It is well recognized that rapidly restoring range of motion and rebuilding muscle strength is critical following any type of knee procedure.<sup>8,22,27,37</sup>

Von Riemke, in his presidential address to the Danish Surgical Society stated in 1926 that "all joint affections...should be moved and movement should begin on the first day, should be slow, and as much as possible, it should be continuous".<sup>26</sup>

Based upon his experimental investigation on rabbit knees in the early 1960's, Salter <sup>26,27,34,35</sup> came to the conclusion that immobilization is unhealthy for a joint. He was of the opinion that intermittent motion was healthier for a knee joint as compared to immobilization, and he arrived at the conclusion that perhaps continuous motion might be better. He was quick to realize that skeletal muscle had easy fatigability so that if one were to have continuous motion, it would have to be passive rather than active.

There are several ways to describe continuous passive motion but one definition can be, "a machine with an external motor which passively moves a joint through a pre-set arc of motion.<sup>17</sup>

- † Co-Founder & Medical Director
- \* Co-Founder, President & CEO Halley Orthopedics Columbus, Ohio www.x10therapy.com

This article has been written to describe a newly designed rehabilitation machine, called the "X-10". The X-10 works in a radically different manner from the previous 'traditional' continuous passive motion machines used in rehabilitation of the knee.

O'Driscoll has pointed out that early research on continuous passive motion was based upon the theory that it promoted healing of articular cartilage. <sup>26,34,35</sup> However, throughout the mid 1980's and 1990's, the major use of traditional continuous passive motion has been to prevent stiffness following total knee arthroplasty.

In the 1990's there was an explosion in the use of continuous passive motion with many early advocates supporting such treatment.<sup>2,7,11,12,16,18,21,22,29,32,36,37</sup> However, with time and appropriate evaluation of results, a significant group of detractors stated CPM was of no benefit in the rehabilitation of total knee arthroplasty because results were the same at six months to one year following surgery, whether or not CPM was used. <sup>3,5</sup> <sub>6,8,9,10,14,17,18,19,20,21,24,25,29,31,32,33,36</sub>

O'Driscoll<sup>26</sup> suggested perhaps it mattered how CPM was used and to better understand the potential for continuous passive motion one must understand the pathophysiology. It is important to fully understand the theory behind the development of fibrosis before interpreting the past experience with continuous passive motion.

### Pathophysiology of Joint Stiffness

The pathophysiology of joint stiffness, as theorized by O'Driscoll<sup>25,26</sup>, describes the four stages of fibrosis with progression of the first three stages leading into the fourth stage of fibrosis characterized by thick hard dense scar formation.

Stage one: Bleeding into the joint is the first stage of fibrosis. This occurs in a matter of minutes to hours following knee surgery, resulting in the distention of the joint capsule and periarticular swelling. The maximum capsular capacity of the human knee joint occurs at 35 degrees of flexion. This swelling leads to very high intraarticular hydrostatic pressure and any movement from the maximum capacity of the joint increases these pressures which cause severe pain. The patient attempts to hold the knee in the position of maximum capacity so as to minimize the pain created by any increase in pressure. This selfprotective mechanism to pain contributes to the early loss of motion in flexion and extension.

Stage Two: The second stage is edema which occurs in a matter of hours or days. The edema is caused by mediators released from platelets as well as injured or dead cells. These cause nearby blood vessels to dilate and leak plasma resulting in swelling of the periarticular tissues, thereby decreasing the compliance of this tissue making it more difficult to move the joint.

The effects of these first two stages are a result of fluid accumulation. This is why it is so important to start treatment early to pump the fluid from the knee and periarticular tissues as soon as possible. In the next two stages it is significant to note this fluid is replaced by an extracellular matrix.

Stage Three: The third stage occurs in a few days to weeks with the formation of granulation tissue which has the physical properties between that of a well-formed blood clot and loose areolar fibrous tissue. That stiffness, originally caused by fluid accumulation, is now due to the deposition of a solid extracellular matrix.

Stage Four: As the collagen hardens it becomes more and more difficult to eliminate. This progression typically finalizes into the fourth stage of fibrosis creating dense hard scar tissue which can permanently impede mobility within two to four weeks, when many patients are just beginning physical therapy.

O'Driscoll et al<sup>25</sup> have shown that flexion and extension of the knee create changes in pressure in a sinusoidal fashion which results in a "pumping effect" which is responsible for clearing blood and edema from the joint.

When patient physical therapy typically begins, lack of range of motion is not normally a focus point during the first few weeks after surgery. The knee is swollen, stiff, painful and the patient is simply trying to walk short distances. By the time outpatient physical therapy begins (on average 3-4 weeks post-TKA) it is often not possible to prevent the accumulation of fluid in the periarticular tissue. Failure to achieve a full range of motion in the immediate postoperative period, combined with permitting the accumulation of even relatively small amounts of periarticular blood and edema, permits collagenous scar tissue formation. Full range of motion might never be completely achieved.

A device and method for early removal of fluid from the periarticuar tissue prior to collagen formation would therefore be desirable. Treatment should begin early, working in the terminal range of flexion and extension, and continued until all swelling of the knee has been eliminated.

### The X-10: New Rehabilitation Technology

The X-10 is a new technology that will allow continuous passive motion to work as originally desired, but never accomplished with the traditional CPM machines.

The traditional continuous passive motion (CPM) machine undesirably sets limits on extension and flexion and operates only within those limits. If the limits are set too aggressively, the joint can experience excess stress, leading to pain and potential injury, while too little pressure results in insufficient progress. Typically, the traditional CPM machines are used to exercise a specified range of motion limited by fixing the target angles within the patient's existing range of motion, which is already achievable by the patient.

It is best to work in the terminal range of flexion and extension as this is more effective in pumping the fluid from the joint.<sup>25,26</sup> Working in the midrange of motion, already achieved by the patient, becomes self-limiting and can undesirably leave periarticular fluid about the joint and prevent meaningful progress. In fact, it can be detrimental as this retained fluid can ultimately lead to undesired scar formation.

Traditional continuous passive machines (CPM) depend upon pre-programmed flexion and extension values to determine the extent of motion. These machines will push blindly and have no pressure feed-back and no pressure variability.

The traditional CPM machine is unable to provide a high or low amplitude 'pause' at the extremes of the patient's range of motion. The X-10 slows down and literally coasts into the last five degrees of

terminal flexion or extension, at which time it stops for a programmed number of seconds. This allows the tissue to maintain a 'stretch' for the individual's programmed time of stretch and relaxation.

Another issue is that not all patients respond in the same manner to their therapy. Some patients tend to form scar tissue more rapidly and this hypertrophic scar formation leads to loss of function at a faster pace than normal.

Orthopedic surgeons have always been leaders in the development and use of new technology in the treatment and care of their patients. It is our goal to continue this tradition into the field of joint rehabilitation offering a technological therapy aid to help the surgeon or physical therapist provide better care to their patients.

Understanding the basic pathophysiology of fibrosis and the importance of early use of continuous passive motion, brings us to the problem associated with the use of traditional CPM machines. . .Pain! Pain prevented patients from starting early and working in terminal range of extension and flexion.

The X-10 works in a radically different way than a traditional CPM machine. Rather than having the knee move back and forth between two fixed points at a constant pressure (like the traditional CPM machine), the X-10 uses the newly patented technology of Variable Pressure. It uses threshold pressure to operate, allowing the knee angle to be variable. This customizable "pressure threshold" is set by identifying the maximum pressure tolerable within the patient's comfort zone. The primary focus is on the patient's current terminal range of extension and flexion. Large arcs of motion, working at terminal limits, greatly enhances the pumping action eliminating blood and periarticular fluid while gently stretching and re-aligning the muscle fibers.

### How Does The X-10 Control Pain?

By limiting pressure, pain is taken out of the equation. The "Variable Pressure" technology allows for customizable "Pressure Threshold" to be set by identifying the maximum pressure tolerable within the patient's comfort zone. Never will the pressure exceed this 'ceiling' pressure which protects the patient and provides assurance to the

patient that there will be no sudden increased pain experience throughout the entire rehabilitation process. As the patient quickly becomes accustomed to the pressure limit, additional pressure can be added in one-pound increments as tolerated by the patient. This increase in pressure increases further the current range of motion attained.

The idea behind the X-10 is the patient can work at a pressure slightly less than a level that will cause pain. After several cycles of the machine the patient will plateau in motion levels as the patient has quickly adjusted to that particular pressure thereby allowing the therapist to increase the pressure, as needed, in one-pound increments. These incremental increases in pressure allow for further progression of motion. Thus, an increase in pressure increases motion. That motion plateaus. Next, the pressure is increased in one-pound increments, as tolerated by the patient, which increases motion that will plateau. This process is repeated over and over until the final desired range of motion is achieved. This process is very gentle and creates very little discomfort for the patient.

### The X-10 Has Four Flexibility Programs

There is a "warm-up" program which is very popular with patients. It functions at any range of motion short of terminal flexion and extension. Once warmed up the patient can proceed in working at terminal limits which is the second program. In this program the machine makes a full cycle between flexion and extension at terminal limits. The third and fourth programs have to do with specifically working at either end of the spectrum in flexion or extension thereby short-cutting a full cycle. This was designed to save valuable rehabilitation time. For example, if the patient has full extension, there is no need to work on extension. The machine can be programmed in a short cycle working only in terminal degrees of flexion. Vice-versa, if good flexion has been achieved and there is lack of full extension, the machine is programmed to work the short cycle in terminal extension.

The ability to prevent flexion contractures is a result of the two modes of using terminal extension with the X-10. The X-10 was originally designed to simply prevent flexion contractures: thus the name reflects 'X-10' for 'extend', to prevent flexion contractures.

### Strengthening

The X-10 has two programs to allow for eccentric and concentric strengthening of the thigh to be used either before or after surgery. Before surgery, a baseline record of strength can be identified. From this point a patient can proceed with strengthening programs prior to surgery. This can prevent any further loss of strength resulting from the basic disease process or from the normal decrease in strength following any surgical procedure.

"Quadriceps strength<sup>27</sup> was the strongest predictor at one year...(and) functional decline may be delayed with adequate quadriceps training. Followup of these patients continues to discern the longterm impact of strengthening interventions". When using strengthening programs after surgery, we recommend waiting three weeks. Though the machine is gentle and can work in one-pound increments of pressure, we do not want to risk injury to the capsular repair until sufficient healing has occurred.

### Patient Safety

Patient safety has always been top priority in the development of the X-10. There are five built-in safety mechanisms, including eStop, that allows the user to stop the motor and treatment immediately.

### X-10 Is Not Cookie Cutter Therapy!

We recognize that patients respond differently to therapy for a variety of reasons.

One of the highlights of this machine is its ability to allow patient therapy to be individualized.

Beginning early treatment allows the healthcare provider to identify any potential problem that will require focusing upon special treatment.

### Additional Benefits

The X-10 incorporates a visual computer module which collects information while the patient is on the machine, recording initial and final range of motion for each session, time of use, and pressures used for treatment. This information can be printed and used for billing purposes, saving physical therapists considerable time in documentation, or it can be electronically sent to physicians involved in the care of the patient. Lastly, the computer module provides real-time positional location of the leg,visualized on the computer screen, allowing patients to focus on their rehabilitation at the very instant of treatment, acting as a "coaching" aid for them during their treatment.

### Comfort

The X-10 answers two of the criticisms of the traditional CPM machine. The first is that the patient lies in bed in a supine position.<sup>1</sup> With the X-10 the patient is comfortably seated in an attached specially designed chair which can swivel into a locked position to allow treatment of the right or left knee. The chair is so designed as to relieve pressure from the hamstring muscles and sciatic nerve to avoid any contribution to the development of back pain. The second criticism<sup>3</sup> of the traditional CPM machine is the recorded motion in extension and flexion is usually less than the "true" range of motion. With the X-10, the exact position of the leg in space is computer generated, based upon the position of the arm of the mechanical leg holder, and is accurate within 1-2 degrees.

### **CPM Case Studies**

The X-10, having been recently developed, has not allowed for large numbers of patients for study. However, there has been a tremendous positive response from all patients who have used the X-10. We can report three classic patient scenarios, representative of conditions we, as surgeons, have to face in the care of our patients. Each patient scenario has been carefully studied.

The first scenario is a right knee that had advanced long term loss of flexion. Ritter et al state that patients with less than 75 degrees of flexion before surgery were less likely to improve postoperatively.<sup>5,29</sup>

A second scenario, a left knee (the opposite knee in the same patient) had a more normal pre-operative range of motion and should represent the course of the typical average patient knee.

The third case scenario involves a patient who had received regular physical therapy for three weeks, and plateaued, and was dissatisfied with her range of motion. This case started later in therapy with the X-10 and suggests benefit can be attained even when starting later than normal.

Case # 1: A severely limited right knee joint with marked loss of flexion before surgery, present for 16 years, had a pre-op AGE 15 degrees and AGF of 70 degrees. The patient began using the X-10 at home 3 days after surgery; it was used 2-3 times / day for 15-20 minutes, followed by ice therapy. That knee reached full extension as well as 108 degrees of flexion within 3 weeks allowing the patient to go up and down stairs in reciprocal fashion and ride a stationary bicycle, two things she had not been able to do for 16 years.

Case # 2: This is the same patient with a more 'typical' left knee (AGE 15 degrees and AGF 115 degrees), operated upon six weeks following her first knee surgery. Again, she started at home on post-op day 3, and within one week from surgery, was off all external support and had reached full extension and 116 degrees of flexion.

Case #3: A middle aged female with goal of returning to golf, tennis, etc., began using the X-10 in an outpatient clinic 3 weeks post surgery after experiencing disappointing results with routine physical therapy alone. At that time her AGE was 5 degrees and AGF 89 degrees. After 4 weeks of X-10 she had AGE of 0 degrees and AGF of 134 degrees having increased her total ROM by 50 degrees while using the X10.

### Conclusion

It seems a reasonable assertion that if a patient can comfortably begin rehabilitation within two to three days following surgery (made possible because of *Variable Pressure*) there is reasonable expectation that patients will achieve a greater range of motion in a shorter period of time. However, this is a secondary goal. We are thinking in "revolutionary" terms. It is our primary goal that patients will have a more rapid recovery allowing them to become totally independent, and if a member of the work force, able to return to work in a shorter period of

time following surgery. Our dream is that time frame will be four to six weeks rather than the traditional three months. If this becomes possible it will achieve considerable health care savings.

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### Pseudotumor in Metal-on-Polyethylene Total Hip Arthroplasty

Terry A. Clyburn MD<sup>†</sup>

#### Abstract:

Pseudotumor formation is a rare, but severe potential complication of total hip arthroplasty. Focus has been on metal on metal articular surfaces as the primary cause. Also known as Adverse Local Tissue Reactions (ALTR's), previous reported cases have presented as infections. Prior ALTR's of non-metal on metal articulations have been reported and of cases in which modularity of the neck may have been a factor. We report on a case of a nonmodular neck with a metal on polyethylene articulation which presented as an infection, but in which ALTR was the causative factor.

### Introduction

Total hip replacement is a common and highly successful procedure. Foreign body reaction was recognized early in the history of hip arthroplasty and was initially thought to be solely the result of poly-methyl-methacrylate (PMMA). In fact this was termed "cement disease". Later, even in uncemented implants, severe osteolysis and soft tissue damage was observed and clearly polyethylene wear was the causative factor. Polyethylene wear disease leading to osteolysis became such a significant issue that extensive work by many researchers and extensive resource expenditures by industry lead to the development of ceramic-on-ceramic, metal-onmetal and "improved polyethylene".

Case reports and reports of higher than expected failure rates have been reported in some metalon-metal implants leading to recalls, law suits and a significant downturn in their use.<sup>1,2,3</sup> Most have presumed that the actual metal on metal articulation was the source of elevated ion levels and thus local tissue reactions. There are however, reports of cases of ALTR in non-metal on metal total hips.<sup>4,5,6,7</sup>

Modular necks introduce an additional interface which may contribute to local metal debris and ion loads.<sup>8,9</sup> A recent case report documents the stemneck interface as a probable cause of ALTR in a ceramic-on-polyethylene articulation.<sup>10</sup>

We report a case of ALTR in which the head neck junction is a non-modular femoral neck stem with a metal on polyethylene bearing. Surgical findings and photographs show that the metal source was the head-neck articulation.

### **Case Report**

A 52 year old female underwent total hip arthroplasty in 2007 at another facility, utilizing a Accolade 52 mm acetabulum with a Trident X3 standard polyethylene and a metal 32 mm +4 head on a size 2 Accolade TMZF HA stem. (Stryker, Kalamazoo, Michigan) The patient did well until August of 2012 when she experienced increasing pain in the right groin and buttocks region. Ambulation became increasingly difficult. Workup in her home facility including an x-ray which revealed a stable implant, but with evidence

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of osteolysis about the ischium (Figure 1) and a Technetium-three-phase-Bone scan which showed increased uptake about the greater trochanter. Due to increasing pain, an aspirate was performed under fluoroscopic guidance and 1 ml of purulent appearing material was obtained. Cultures were sent, but no growth was observed. The patient was advised to return for further followup should pain continue.



Figure 1: Note the severe osteolysis about the greater trochanter, calcar region and ischium.

The patient presented to our facility wheel-chairbound in severe pain. Her temperature was 100.5 F, she denied taking antibiotics but was taking large doses of Hydrocodone/Acetominophen. She had a palpable and large mass on the lateral aspect of her hip which was felt to be fluctuant. Her ESR was 40 and CRP was 46. A needle aspiration in the office with an 18 gauge needle produced no fluid. The patient was admitted to the hospital and a Jamshidi needle (CareFusion, Chicago, IL) was used. With the large bore needle over a 120 mls of fluid was collected and remarkably a large amount of fluid was lost as it literally shot to the ceiling before the syringe could be attached. The material appeared to

be grossly purulent. The fluid however showed only 2000 WBC's.

Although the presentation was somewhat unusual, the patient's pain was so severe and the aspiration so profound we assumed she had a non-standard presentation of an infected total hip. She was taken to the OR for explantation and an antibiotic loaded PMMA implant (PROSTALAC). (Figure 2). Cultures from the aspirate and



Figure 2: PROSTALAC in place. Note thin shell of greater trochanter and fragmentation about abductor attachment points.

also from the surgical specimens were negative, but permanent pathology was typical of ALTR. (Figures 3,4,5).



Figure 3: Note chronic inflammation with plasma cells and lymphocytes.



Figure 4: Taken from the backside of the acetabulum with fragments of bone with ischemic necrosis, chronic inflammatory tissue and dense fibrous tissue.



Figure 5: Note primarily chronic inflammatory changes, but with small areas of acute inflammatory change.

Observations at the time of surgery were that the pseudotumor was massive and again under extreme pressure. The lesion was noted to be immediately under the skin and when touched with the #10 scalpel, purulent appearing fluid reached 3 feet above the patient. Figure 6 is taken of the pseudotumor after removal of this fluid. The tissue



Figure 6: The pseudotumor is seen posterior to the greater trochanter. This photo was taken after at least 200-300 cc of purulent appearing fluid had been removed.

of the pseudotumor appeared to be very aggressive. Significant damage was noted about the abductor attachment to the greater troch, although the tendons remained attached, much of the trochanter was denuded of attachments. The osteolysis had resulted in marked loss of the inner aspect of the greater troch and had eroded around the stem extensively. (Figure 7). There was marked osteolysis about the



*Figure 7: Note the inflammatory tissue about the stem and the marked osteolysis about the entire proximal femur and greater trochanter.* 

inferior aspect of the acetabulum. There was mild metallic staining of all of the removed tissue. The metallic femoral head was easily removed from the femoral stem. We observed and photographed evidence of metal debris and damage at this interface which would seem to reveal evidence of movement. (Figures 8, 9). The femoral stem did have areas of osseous integration, but was easily removed without need for an extended trochanteric



Figure 8: Note the metallic staining and obvious fretting about the trunion.

osteotomy. The cup was also relatively easily removed with Moreland Acetabular chisels (Innomed, Savannah, GA). The back side did

show small areas of osseous integration, but this was minimal. (Figure 10).

Figure 9: Note the damage inside the head

Again, as we presumed this to be an infection case, we chose to place the PROSTALAC and await cultures. All cultures including those for Acid Fast Bacteria and Fungus were negative at

with severe fretting.



Figure 10: Note the small areas of osseous integration with primarily no or only fibrous ingrowth.

6 weeks. The patient was not treated parenterally other than the first 24 hours of prophylactic antibiotics after the PROSTALAC and ESR and CRP were 3 and 0.34 respectively at the time of reimplantation. At the time of reimplantation of the hip, all tissues had a benign appearance, frozen section revealed "mild" inflammation, but with 1-2 polymorphonucleocytes (PMN's) per high power field (HPF).

We chose to use a ceramic on highly cross-linked poly and we augmented the acetabular fixation with screws. (Figure 11).



Figure 11: Immediate postop radiographs of reimplanted prosthesis.

### Discussion

Virtually all modern total hip stems incorporate a Morse Taper allowing for adjustability of femoral head diameter, head length and allow for material choices. There is variability of design of the Morse taper. The stem used in this reported case was a V-40 taper. In this case, the head size was not particularly large at 32 mm. Theoretically, as the diameter of the head is increased, and thus the lever arm about the Morse Taper, rotational forces upon the Morse Taper interface may increase. Also in this case, a plus 4 mm head length was used. Theoretically, it is possible that with plus size head lengths, the actual contact area of the Morse Taper interface would be reduced, resulting in less stability, movement and fretting. In this case, the stem was a HA coated stem. The stem appeared to be stable with evidence of bone ingrowth, but there are reports of HA material resulting in adverse local tissue reactions.<sup>11</sup> Although it would be impossible to argue that the HA could not have been a factor in the failure and Pseudotumor formation in this case, the findings about the Morse taper were quite profound and would be most likely the cause of failure. No gross particulate matter was noted in the pathology sections.

In my practice, I recommended a metal-on-metal articulation for the majority of my patients from 1998 until 2011. Due to reports, published data and a generally negative legal environment with regard to metal-on-metal: I have reduced the use of MOM to less than 5% of my cases. I have not performed a revision, and I am not aware of any of my metalon-metal patients having undergone revision as a result of ALTR. Ironically, the only revision I have done which was done for Pseudotumor and with histological findings of ALTR was in this reported case with a metal-on-polyethylene articulation. Clearly, we must continue to carefully document all failures, study them and report them. We must be cautious to avoid making broad assumptions when failures occur. It is apparent that there are multiple modes of failure and that the metal-on-metal articulation alone is not the sole cause of failure.

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### Range of Motion In High Flexion Total Knee Arthroplasty vs. Standard Posterior Stabilized Total Knee Arthroplasty A Prospective, Randomized Study

George N. Guild III, MD<sup>†</sup>, Sameh A. Labib, MD\*

### Abstract:

Range of motion after knee replacement is an important factor in overall outcome. The purpose was to compare motion in patients receiving high flexion prosthesis vs. standard prosthesis. 24 high flexion and standard knee prostheses were used. Patients were followed for two years and evaluated prospectively. The mean HSS was 80.4 for the standard group and 80.7 for the flexion group. At two year follow up the standard prosthesis group had mean flexion of 113°. The high flexion prosthesis group had mean flexion 106°. No knee had aseptic loosening, infection, or osteolysis. At two year follow up, there were no significant differences between groups with regard to range of motion, clinical outcome, or radiographic evaluation. Keywords: total knee arthroplasty, high flexion, range of motion

### Introduction

Range of motion in total knee arthroplasty is a key determining factor in a patient's overall functional outcome.<sup>1</sup> The fact that most knees do not flex more than 120° after surgery has been studied extensively, but no one theory sufficiently explains this phenomenon.<sup>2,3,4,5</sup> To address deep flexion issues after total knee arthroplasty high flexion designs have been developed in the last decade.

The Nexgen LPS-Flex Total Knee system (Zimmer, Warsaw, Indiana) has three principle design modifications compared to the LPS standard system. First, to address potential point loading of the posterior femoral condyle on the polyethylene liner at flexion angles of up to 155°, the posterior femoral condyles have been extended by 2mm. The radius of the posterior femoral condyles has been extended to provide larger tibio-femoral contact area in high flexion (fig. 1). The outside A/P dimension of the component does not change as a result of these modifications. The second modification is an increase in cam height. This greater jump height is to prevent tibio-femoral disassociation



Figure 1: Diagram of a cruciate retaining standard total knee arthroplasty compared to high flexion total knee arthroplasty design at 155° of flexion this figure is reproduced with permission from Zimmer (Warsaw, Indiana)

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Figure 2: Diagram of difference in cam height and theoretical increased jump distance in standard total knee prosthesis vs. high flexion prosthesis this figure is reproduced from Zimmer (Warsaw, Indiana)

during flexion from 120° to 155° (fig. 2) In some posterior stabilized knees, as the knee goes into deeper flexion, the cam on the femoral component begins to move superiorly on the spine of the tibial articular surface. To address this, the shape of the cam on the LPS-Flex Femoral Component has been modified to contact the spine more inferiorly and thereby provide a greater jump height at flexion angles greater than 130°. The third modification is that the anterior flange of the femoral component has a larger deeper cutout to provide increased conformity for patella-femoral tracking and the anterior lip of the polyethylene has a cut out for the patellar tendon.

Theoretically these design modifications may lead to better postoperative range of motion. Several studies have shown a difference between standard and high flexion prostheses, but other studies have shown no difference. A previous meta-analysis including six studies did show a significant difference in favor of the high flexion design but, only two of those studies were randomized controlled trials.<sup>6</sup> In another systematic review no difference was found between the prostheses but, data synthesis and quantitative analysis were not performed.7 Consequently, controversy remains over designs with high flexion modifications. Thus, we performed a prospective randomized trial to assess differences in pain, functioning, and range of motion in the Nexgen LPS and Nexgen LPS-Flex total knee systems.

### Materials and Methods

Between 2004 and 2006 the senior Author (S.L.) performed 24 consecutive primary total knee arthroplasties in 23 patients at the Atlanta VAMC. No patient was lost to follow up. One patient was eliminated from the study due to early (< 6 months) aseptic loosening of the tibial component requiring revision. The study was approved by the institutional review board and informed consent was obtained. Randomization of the total knee prosthesis, NexGen LPS standard or

High Flexion, was determined on a sequential pool on the basis of a table of random numbers. The mean age of the patients at the time of operation was 60.5 years (range 45-74) and all were veterans. 23 patients were men and 2 were women. 13 patients had previous knee surgery (9 open meniscectomy, 3 arthroscopic chondroplasty, 1 arthroscopic loose body removal) The preoperative diagnosis for 18 patients was osteoarthritis, 3 had post-traumatic arthritis, and 2 had rheumatoid arthritis. Pre-operative tibio-femoral angle was measured in all patients and there were no valgus knees.

The surgical technique for all procedures was a midline skin incision approximately ten centimeters with a median parapatellar arthrotomy. The cruciate ligaments were sacrificed in all patients. The magnitude and angles of the bony resections were standardized across treatment groups. The distal femoral resection was made with an intramedullary guide to resect 10 mm of bone from the most prominent femoral condyle at an angle of 5° of valgus. The tibial resection was made using an extramedullary guide with the goal of producing a neutral cut in the coronal plane and 7° of posterior slope in the sagittal plane. The anterior, posterior, and Chamfer cuts were made with a posterior femoral condylar referencing guide in 3 degrees of external rotation. In the NexGen High Flexion group, 2 additional mm of posterior femoral condylar bone was resected compared to the NexGen LPS Standard group. Posterior condylar osteophytes were resected in all patients. Ligament balancing was aided with the use of spacer blocks

with the goal of creating symmetric gaps of equal magnitude in flexion and extension. Superficial MCL release was required in 7 patients including four in the high flexion group and three in standard group. The amount of bone removed during patellar resection was equal to or slightly greater that the thickness of the patellar component. All implants were cemented. The capsule was closed in 30 degrees of flexion in all patients.

All patients had patient controlled analgesia immediate post-operatively and CPM machine's applied postoperative day 0 for at least 6 hours per day. Patients were allowed weight bearing as tolerated and worked with physical therapy beginning post operative day 1.

Clinical and radiographic evaluations were taken 6 weeks post-operatively, 6 months, one year, and two years. Each knee was rated pre and post operatively to the systems of the knee society and the Hospital for Special Surgery. Patients also completed the Short Form 36 (SF-36) questionnaire.

Active range of motion was determined preoperatively and post-operatively with a 12 inch

goniometer at 6 weeks, 6 months, 1 year, and two years. Clinicians were blinded with regard to which total knee prosthesis was implanted.

Radiographic evaluations were made preoperatively and post-operatively by obtaining AP, Lateral, and skyline views. Evaluations were made at 6 weeks, 6 months, 1 year, and 2 years. Assessments were made based on limb alignment and component position. Radiolucencies and bone loss were also noted on AP, Lateral, and sunrise views. Skyline views were also examined for patellar tilt, subluxation, and dislocation.

### Results

#### **Clinical Outcomes**

#### Knee Score

The pre-operative and post-operative knee scores are summarized in Table I. The Hospital for Special Surgery (HSS) and Knee Society scores (KSS) did not differ significantly between the two groups pre-operatively (P= 1.00000 and p= 0.7404, respectively) or post-operatively (p = 0.9177 and

Table 1: Knee Outcome Scores											
		Pre	eop	6 week		6 month		1 year		2 year	
variable	Group	mean±sd	p-value	mean±sd	p-value	mean±sd	p-value	mean±sd	p-value	mean±sd	p-value
		55.00		63.30		71.45		75.82		80.42	
1166	STD	±12.38	1 0000	±12.85	0.0750	±11.41	1 0000	±14.08	0 4124	±10.48	0.0177
пээ		56.95	1.0000	64.09	0.9739	72.4	1.0000	71.22	0.4134	80.76	0.9177
	Flex	±8.69		±9.63		±9.25		±12.14		±9.24	
		47.92		58.64		69.17		71.67		78.64	
VCC	STD	±14.99	0.7404	±16.90	0 5227	±18.44	0.5206	±14.29	0 2264	±19.12	0.2212
K35		49.17	0.7404	52.5	0.5557	63.75	0.5206	57.73	0.2264	69.09	0.2313
	Flex	±11.45		±24.07		±16.11		±25.24		±18.55	
KSS: knee s	ociety score;	Hospital Spec	ial Surgery; S	STD: indicated	l Conventiona	al Prostheses;	Flex: indicate	s high flexion	prostheses; s	d: indicates st	andard

deviation

Table 2: Mean Range of Motion											
		Pre-operative		6 weeks		6 months		1 year		2 year	
	group	Mean+/- sd	p-value	Mean+/- sd	p-value	Mean+/- sd	p-value	Mean+/- sd	p-value	Mean+/- sd	p-value
Flexion	STD	113.00±15.67	0.0895	107.45±14.31	0.0814	112.25±13.71	0 3089	115.08±16.98	0.0376	113.00±10.09	0 1853
Tiexion	Flex	101.83±11.34	0.0095	92.42±24.77	0.0011	105.42±9.63	0.5005	104.73±11.47	0.0570	106.27±12.17	0110000
Extension	STD	7.58±8.22	0.8735	11.55±7.35	0 3693	6.67±2.96	0.7659	4.17±2.62	0.7711	1.27±3.20	0.6933
Extension	Flex	7.33±7.60	0.0755	9.42±9.34	0.5075	4.58±9.09	0.7055	2.45±8.50	0.7711	0.64±7.78	0.0933
CTTD			a ·	1							

STD: standard prosthesis; Flex: high flexion prosthesis; SD: standard deviation

p = 0.2313, respectively). The mean pre-operative HSS score for the standard knee prosthesis group was 55 (mean sd+/- 12.38) and 56.95 (mean sd+/-8.69) in the high-flexion group. In the NexGen LPS group, the mean postoperative knee score was 80.4 (mean +/- sd 10.48) for the Hospital for Special Surgery Score and 78.6 (mean +/- sd 19.12) for the Knee Society Score. In the NexGen LPS Flex Group, the mean postoperative knee score was 80.7 (mean +/- sd 9.24) for the Hospital for Special Surgery Score and 69.1 (mean +/- sd 18.55) for the Knee Society Score.

### Range of Motion

The mean pre-operative and post-operative range of motion is summarized in Table 2. Preoperatively, the mean flexion contracture was  $8^{\circ}$  (mean +/- sd 8.22°) for the NexGen LPS Group and 8° (mean +/sd 7.60°) in the NexGen LPS Flex Group. At two years the mean flexion contracture in the LPS group was  $1.2^{\circ}$  (mean +/- sd  $3.2^{\circ}$ ) and  $0.6^{\circ}$  (mean +/- sd 7.78°) in the NexGen LPS Flex Group. The flexion preoperatively in the Nexgen LPS Group was 113° (mean +/- sd 15.67°) and 102° (mean +/- sd 11.34°) in the Nexgen LPS Flex Group. At two year follow up, the mean post-operative flexion in the standard group was 113° (mean sd+/- 10.09) and 106.2° (mean  $sd+/-12.17^{\circ}$ ) in the high flexion group. There was no significant difference between the two groups with regard to preoperative flexion contracture (p = 0.8735) nor at the two year follow up (p = 0.6933). There was also no significant difference with regard to flexion between the two groups preoperatively (p = 0.0895) and at the two year follow up (p = 0.1853)

### Quality of Life Outcomes

In the NexGen LPS Group the SF-36 Physical Scores were 30.29 (mean +/- sd 6.11) preoperatively and were 39.14 (mean +/- sd 6.66) at the two year follow up. The Nexgen LPS Flex Group had SF-36 Physical Scores of 30.39 (mean +/- sd 10.89) preoperatively and 43.72 (mean +/- sd 11.14) at the two year follow up. There was no significant between the SF-36 Physical Scores between the two groups preoperatively (p = 0.5508) or at the two year follow up (p = 0.3653) In the NexGen LPS Group the SF-36 Mental Score was 46.70 (mean +/- sd 10.70) preoperatively and 50.16 (mean +/- sd 9.87) at the two year follow up. In the NexGen LPs Flex group the SF-36 Mental Score was 49.15 (mean +/- sd 14.77) preoperatively and 47.19 (mean +/- sd 14.15) at the two year follow up visit. There was no significant difference between the two groups SF-36 Mental Scores preoperatively (p = 0.5041) or at the two year follow up (p = 0.7427)

### Radiographic Evaluation

There were no significant differences between the groups with regard to the position of the femoral and tibial components in the coronal and sagittal planes or varus and valgus alignment of the knee. There was also no significant differences between the patella angle (the angle between a line along the patellar cut surface and a line joining the most proximal margins of the femoral condyle of the component on the skyline radiographs), the amount of tibial surface area covered by the implants, or the mean level of the joint line (figs. 3 and 4). In the NexGen LPS Group one patient had patellar bone loss on the skyline view at the two year follow up. One patient in the NexGen LPS Flex Group had tibial bone loss at two year follow up. There were no other findings of radiolucency or bone loss on



Figure 3: Anteroposterior radiograph of fixed bearing posterior stabilized high flexion prosthesis

Figure 4: Lateral radiograph showing posterior stabilized fixed bearing high flexion total knee arthroplasty

AP, lateral, or skyline views at the two year follow up in either group.

### Complication Report

Of the 24 arthroplasties performed, one patient in the NexGen LPS Flex Group developed arthrofibrosis requiring manipulation under anesthesia ten weeks after the index procedure. Afterwards with aggressive PT the patient achieved a functional range of motion. Another patient was excluded from the study secondary to early aseptic loosening of the tibial component requiring revision total knee arthroplasty.

### Discussion

Despite advancements in surgical technique, implant design, and postoperative management, limitation of postoperative range of motion continues to be a relatively common complication.<sup>8</sup> Although early studies reported stiffness in >50% of patients with TKA<sup>9</sup>, the true incidence appears to be 8% to 12%.<sup>8,10,11</sup> Biomechanical studies and gait analysis have shown that patients require 67° of knee flexion during the swing phase of gait, 83° to ascend stairs, 90° to 100° to descend stairs, 93° to rise from a standard chair, and up to 105° to rise from a low chair.<sup>12,13</sup> Active patient populations require range of motion for quality of life.

Variables affecting post-operative outcomes from total knee arthroplasty have been extensively studied and can be categorized as pre-operative, intraoperative, and postoperative factors. Preoperative ROM is an important predictor of ultimate ROM after TKA. Ritter and Stringer<sup>14</sup> found that the amount of achieved postoperative flexion correlated with the amount of preoperative flexion. In their study, 8 patients with mean preoperative flexion  $< 75^{\circ}$  achieved mean flexion of 85.6° at 1 year after surgery, whereas 43 patients with mean preoperative flexion of 76° to 95° had mean postoperative flexion of 95.1°. An interesting trend observed in studies of patients with poor preoperative flexion ( $<90^\circ$ ) is that they tend to gain flexion postoperatively; patients with a mean preoperative flexion >105° tend to experience a net loss in flexion, despite retaining greater mean ROM overall.

Ritter and Harty<sup>15</sup> investigated predictors of postoperative range of motion in total knee arthroplasty and reported those requiring a release of the deep and superficial medial collateral ligament had decreased post-operative flexion due to the high degree of pre-operative varus deformity. Furthermore, valgus knees that lacked intraoperative extension contributed to decreased postoperative range of motion.

Intraoperative technical factors may lead to postoperative limitations in flexion, extension, or both. Limitations in flexion or flexion contractures can result from improper flexion-extension gap balancing, malpositioning or oversizing of components, inadequate femoral or tibial resection, excessive joint line elevation, creation of an anterior tibial slope, or incomplete resection of

posterior condylar osteophytes (figure 5). Ritter et  $al^{15}$ reported that removal of posterior osteophytes consistently improved postoperative flexion especially in patients whose pre-operative flexion was  $>105^{\circ}$ . Inadequate distal femoral cut with a pre-operative posterior capsular tightness can lead to a tight extension

gap and contribute



Figure 5: Lateral radiograph of a cemented fixed bearing cruciate retaining total knee arthroplasty with significant unresected posterior osteophytes impinging on the polyethylene insert preventing flexion

to a post-operative flexion contracture. Tightness in both flexion and extension usually occurs because of technical errors on the tibial side. Failure to resect enough tibial bone or inserting a polyethylene component that is too thick can lead to flexion and extension gap tightness. Overstuffing of the patellofemoral joint can also contribute to a tight extensor mechanism and decreased motion after TKA. This occurs with inadequate resection of the patella or anterior placement of the femoral component.

Postoperative factors that can lead to inadequate knee ROM include poor patient motivation and

compliance, deep infection, arthrofibrosis, patellar complications, complex regional pain syndrome (CRPS), and heterotopic ossification (HO).

Multiple investigations with outcome measures evaluating the effectiveness of high flexion total knee arthroplasty designs have not shown significant difference to its standard flexion counterparts. Kim et al<sup>16</sup> published a prospective randomized trial on bilateral total knee arthroplasty in which high flexion designs were compared to standard posterior stabilized designs. 250 patients with bilateral total knee arthroplasty one being high flexion and one being standard were compared using questionnaires, knee scoring systems, clinical, and radiographic examinations. The authors found no significant clinical differences between groups showing no advantage to the high flexion design. Seon et al<sup>17</sup>, provided a study of 50 knees randomized to high flexion or standard design. These cruciate retaining high flexion implants had femoral alterations with 2 mm of extended femoral condyle as well as polyethylene modifications. The patients were followed prospectively for two years and had similar range of motion, function, and knee ratings. They suggested that high flexion design alone did not improve clinical outcome after total knee arthroplasty. McCalden et al<sup>18</sup>, compared high flexion total knee arthroplasty design to standard design in a study of 100 patients. 50 patients received a high flexion polyethylene design and the group received standard polyethylene insert. After 2.7 years there was no difference of range of motion between implant designs.

Conversely, Minoda et al<sup>19</sup>, prospectively randomized 171 patients with 181 cruciate retaining total knee arthroplasties. There were high flexion groups as well as standard groups followed prospectively for one year. There were no significant differences between groups with regard to range of motion, knee scores, clinical and radiographic data. However, the high flexion group had a higher average range of motion. Gupta et al<sup>20</sup>, demonstrated a greater range of motion post operatively with use of a high flexion rotating platform. Bin et al<sup>21</sup>, showed significantly greater average knee range of motion at one year in those receiving high flexion prosthesis vs. standard prosthesis. This was particularly true in patients with a preoperative range of motion of less than 90.

The current study attempts to standardize preoperative and post-operative factors between standard and high flexion groups in order to analyze the effect of an intraoperative factor; specifically whether modifications to the NexGen LPS alone would influence post-operative range of motion and outcome measures. In this study there was no difference between the two groups with regard to range of motion, knee scores, clinical or radiographic data. These findings support other previous literature that high flexion total knee arthroplasty, as an independent variable, does not correlate with improved clinical outcomes including increased postoperative range of motion. Furthermore a potential drawback of the use of high flexion knee designs with additional 2 mm of posterior femoral condylar resection may present a problem in revision cases with respect to bone stock and flexion gap balancing. These findings underscore the importance of addressing all factors that may potentially influence post-operative range of motion as these design modifications alone did not affect post-operative range of motion.

The present study had some limitations. There were no interobserver comparisons which can lead to bias in interpreting radiographs. Also the small sample size may be underpowered to detect a true difference between the high flexion group and the standard arthroplasty group with regard to range of motion, knee scores, clinical and radiographic data. Other problems with small sample size include larger standard deviations in outcome measures and range of motion measurements. Furthermore, this study contains 21 men and two women which is not an accurate representation of gender makeup of the general population. This study was performed at a Veterans Affairs Hospital which accounts for the gender disparity.

From the current study, high-flexion implant designs do not provide a significant improvement over conventional total knee arthroplasty. Further investigation is required in the future to determine if there are differences in implant survival secondary to different contact stresses between designs. Furthermore, continued study of revision of these implants is imperative as it may affect bone stock and gap balancing in revision situations.

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### Dissolvable Antibiotic Beads in Treatment of Periprosthetic Joint Infection and Revision Arthroplasty

### The Use of Synthetic Pure Calcium Sulfate (Stimulan®) Impregnated with Vancomycin & Tobramycin

Edward J. McPherson, MD, FACS<sup>†</sup> • Matthew V. Dipane, BA<sup>†</sup> • Sherif M. Sherif, MD<sup>†</sup>

### Abstract:

This study reviews the clinical results using commercially pure, synthetic antibiotic-loaded Calcium Sulfate dissolvable beads (Stimulan, Biocomposites, Ltd., Keele, UK) in 250 cases of aseptic and septic revision total hip and total knee arthroplasty. A set protocol of Vancomycin and Tobramycin antibiotic was used in all cases. The rate of wound drainage in this series was 3.2%. Wound drainage was generally seen in cases using higher bead volumes. The incidence of heterotopic bone formation was 1.2%. There were nine failures in this study, six of which were due to infection. We feel that commercially pure, synthetic antibiotic-loaded dissolvable beads are an acceptable delivery tool for local antibiotic delivery in aseptic and septic revision joint arthroplasty of the hip and knee. Further studies are needed to examine the potential of improving outcomes of periprosthetic joint infection with this particular local antibiotic delivery system.

**Key words:** *Stimulan, Calcium Sulfate, Antibiotic Beads, Periprosthetic Infection, Revision Arthroplasty.* **Level of Evidence:** *AAOS Therapeutic Study Level IV.* 

### Introduction

Periprosthetic joint infection (PJI) is a devastating complication that is potentially a limb and life threatening condition.<sup>18,19</sup> The extent of the infection is related to many factors including the health of the host patient, the condition of the local soft tissues, and the length of time the infection has been present within the joint. Treatment of periprosthetic infection currently follows established algorithms that have proven successful.<sup>26</sup> Treatment depends upon the presence of the bacterial biofilm which envelops the joint prosthesis and adjacent bone. In an acute infection, the biofilm is not established. Treatment is focused on preservation of the implant,

with radical debridement surgery, modular bearing exchange, copious lavage, and perioperative antibiotic therapy. When a biofilm is present, the infection is considered chronic. In this scenario, the biofilm prevents eradication of bacteria and thus implants must be removed along with a radical debridement of bone and soft tissue. Resection of implants most commonly is performed in a two stage protocol. At some centers that focus on PJI, single stage protocols are utilized. With either

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protocol, success is particularly dependent upon the quality of joint debridement.<sup>42,43,47</sup>

Antibiotic therapy in the surgical treatment of a PJI is an important adjuvant therapy. Antibiotic penetration into the local infected area can be problematic. Specifically, local devascularization of infected tissues can prevent local antibiotic delivery. Additionally, any residual biofilm can shield the area from antibiotics.<sup>4</sup> Local delivery systems offer a solution to this problem. Antibiotic impregnated cement spacers are a useful tool, although a majority of the antibiotic placed into the cement does not elute into the host environment.<sup>23</sup> Non-dissolvable antibiotic polymethylmethacrylate (PMMA) beads can provide higher antibiotic concentrations, but fabrication is tedious. Additionally, it is often difficult to locate and remove all beads at reconstruction.

A local delivery system with dissolvable Calcium Sulfate has been developed to assist in the targeted delivery of antibiotics into the host joint.<sup>5,6,10</sup> Stimulan (Biocomposites Ltd., Keele, UK) is a synthetic hemihydrate form of Calcium Sulfate. It is produced using a synthetic process resulting in 100% purity with no traces of potentially toxic impurities which has been associated with naturally occurring mineral sources of Calcium Sulfate.<sup>3,22</sup> It is biocompatible, composed of hydrophilic crystals, soft after hydration, and disappears on X-rays after two to three weeks when placed within a joint compartment.

Stimulan also has the advantage of delivering a wider spectrum of antibiotic combinations into the joint. It cures at a low temperature, thus allowing heat-sensitive antibiotics to be mixed with Stimulan. This is in contrast to PMMA in which only heat-stable antibiotics can be used. Even with these advantages, there has been concern with using dissolvable antibiotic-loaded Calcium Sulfate.<sup>3,22</sup> The main concern has been with postoperative wound drainage. Prior to Stimulan, dissolvable Calcium Sulfate products were derived from gypsum, a natural product mined and processed into Calcium Sulfate. The processing of gypsum creates a product that has a relatively low pH and contains residual by-products that may illicit an inflammatory reaction when the product is placed into a joint wound. The inflammatory reaction in

turn impedes wound healing and causes a wound to drain.<sup>22,40</sup>

The purpose of this study is to examine the initial review of the use of commercially pure, synthetic antibiotic-loaded dissolvable Calcium Sulfate beads (Stimulan) in their application in treating two groups of patients. One group contains patients with periprosthetic infection. The other contains patients undergoing revision joint arthroplasty. Historically this latter group has a higher known risk of periprosthetic infection.<sup>11,14,15,39,43,47</sup> We review outcomes and complications and compare our findings to previous studies employing processed calcium sulfate derived from gypsum product. To our knowledge, this is the first study reporting on the use of commercially pure, synthetic antibioticloaded Calcium Sulfate in the treatment of two such groups.

### Materials & Methods

Between January 2010 and September 2012, 342 revision THA and TKA procedures were performed. This included aseptic revisions, two stage septic revisions, and one stage DECRA (Debridement, modular Exchange, Component Retention, IV Antibiotic) procedures for acute PJI. During this time we used dissolvable antibiotic beads in 250 of these cases. The antibiotic combination used in this series was a preset protocol consisting of one (1) gram of Vancomycin powder and 240mg of liquid Tobramycin mixed with 10cc of Stimulan powder (see technique below). For two-stage procedures for infected TKA and THA, Stimulan antibiotic beads were inserted both at the time of resection arthroplasty and reimplantation.

Preoperatively, all patients were staged for periprosthetic infection risk according to the Musculoskeletal Infection Society – Americas (MSIS-A) staging system.<sup>26</sup> The integrity of each patient's immune defense system was assessed and all compromising factors were documented.<sup>26,27,8</sup> Aseptic revisions in the MSIS-A classification were considered a Stage Zero. All revision procedures were preoperatively aspirated by the surgeon (ejm) with cell count and culture analysis. Pre-operative Westergren Sedimentation Rates and Quantitative CRP were also obtained on all patients. Clinical scoring was performed on all patients including

Harris Hip and Oxford scores for hips and Knee Society and Oxford scores for knees. Perioperative and post-operative complications were recorded. Radiographs were obtained at 3 months and 1 year post-operatively.

At the time of knee resection arthroplasty, the knee was stabilized with an articulated antibioticloaded PMMA spacer. When the knee was unstable, the leg was stabilized with an antibiotic-loaded PMMA endofusion device with medullary rods inserted into the femur and tibia. Cobalt cement (Biomet, Warsaw, IN) was used in resection and reimplantation/revision procedures. For resections, 5 grams of Vancomycin powder and 3.6 grams of Tobramycin powder were mixed into each 40 gram bag of Cobalt cement. Typically 3-5 bags of cement were used at resection. For revision or reimplantation procedures, 2-3 bags of Cobalt cement were typically used. One gram of Vancomycin powder was placed in each 40 gram bag of cement.

For knee cases, the Stimulan beads were delivered along the medial and lateral gutters of the knee, just before closure. A 10 french silicone Blake drain (Ethicon, Inc., San Angelo, TX) was placed along the lateral gutter and the arthrotomy closed in midflexion over a bump. No beads were placed in the subcutaneous layer. Superficial subcutaneous drains were placed as indicated. The deep drain was always removed between 24 and 36 hours. The superficial drain(s) was removed between 48 and 72 hours. In the two stage septic revision group, a compressive Robert-Jones dressing was placed on the leg for 5-7 days, both at resection and reimplantation. Figures 1 and 2 (see Appendices) demonstrate surgical technique and placement of the Stimulan beads.

Figures 1a - 1e: Radiographs of 65-year-old male who underwent a two-stage revision protocol for a chronic periprosthetic infection of his left TKA. The patient suffers from diabetes.



Figure 1a: Preoperative standing AP radiograph of left TKA. Aspiration cultures grew Staphylococcus warneri and Stenotrophomonas maltophilia.



Figure 1b: Postoperative radiograph of resection arthroplasty. The knee was stabilized with a Vanguard (Biomet, Warsaw, IN) prostalac arthroplasty. 10cc of Stimulan antibiotic beads were placed into the medial and lateral gutters at closure. Note deep and superficial drains placed at closure. This case was one of the initial members of this study, thus accounting for the modest use of beads.



Figure 1c: Preoperative AP radiograph of knees prior to reimplantation. This radiograph was taken 9 weeks after resection arthroplasty. All Calcium Sulfate beads have dissolved. Preoperative aspiration of the knee was negative.



Figure 1d: Postoperative AP radiograph at reimplantation surgery. The knee was reconstructed using the Vanguard revision knee system (Biomet, Warsaw, IN). At closure 20cc of Stimulan antibiotic beads were placed into the knee joint. Again note deep drain placed into knee.



Figure 1e: Standing AP radiograph taken 18 months after reimplantion surgery. All Calcium Sulfate beads have dissolved. The patient remains infection free with knee range of 0-125 degrees.

Figures 2a – 2d: Radiographs of a 57-year-old male who underwent a single-stage revision protocol for Nickel hypersensitivity and clinical pain of his left TKA.



Figure 2a: Preoperative standing AP radiograph. Note well-fixed TKA implants. The patient had knee range of 0-130 degrees, but had a persistently large knee effusion and chronic pain.



Figure 2b: Postoperative AP radiograph of revision TKA. 10cc of Stimulan antibiotic beads were placed into the medial and lateral gutters of the knee. Note drain placed into knee joint at closure.



Figure 2c: Postoperative standing AP radiograph taken 2 months after revision surgery. All Calcium Sulfate beads have dissolved. Also note that the knee effusion has abated.



Figure 2d: Postoperative standing AP radiograph taken 8 months after revision surgery. The knee has regained knee range of 0-135 degrees. Knee effusion remains minimal.

At the time of hip resection, the hip was stabilized with an articulated antibiotic-loaded PMMA hip spacer. The Modular Stage One hip spacer system was used (Biomet, Warsaw, IN). When segmental deficiencies were present in the acetabulum, an antibiotic-loaded PMMA spacer was formed in-situ in the pelvis/acetabulum using a large monopolar head trial as a mold. The cement was secured with two to four 6.5mm titanium cancellous screws placed partly into bone to serve as rebar posts; this prevented spacer displacement. The screws were covered entirely with cement (screwdriver holes were filled with bone wax to allow removal at reconstruction). Cobalt cement was used at resection arthroplasty with the same antibiotic combination as the knee. For revision or reimplantation procedures almost all cases were implanted with cementless reconstruction systems. When a reconstruction cage was used for acetabular reconstruction, the acetabular socket was cemented into the cage with Cobalt cement. One gram of Vancomycin powder was mixed into each 40 gram bag of cement.

For hip cases, the Stimulan antibiotics beads were delivered into the deep hip space inferior to the acetabulum and around the proximal femur. A 10 french Blake Drain was placed just under the Tensor Fascia layer. Additional subcutaneous drains were placed as indicated. No beads were placed in the subcutaneous layer. The Tensor Fascia drain was always removed between 24 and 36 hours. The superficial drains were pulled between 48 and 72 hours. In the two stage septic revision group, a spica brace (set between 20-70 degrees) was used both at explantation (until reimplantation) and reimplantation (4-6 weeks). Figures 3 and 4 (see Appendices) demonstrate surgical technique and placement of Stimulan beads.

Figures 3a – 3c: Radiographs of a 72-year-old male who underwent a single-stage revision protocol for prosthetic femoralacetabular impingement and clinical pain of his right THA.



Figure 3a: Preoperative AP radiograph of pelvis. Note small amount of heterotopic bone near lateral acetabulum and lesser trochanter.



Figure 3b: Postoperative AP radiograph of revision THA. 10cc of Stimulan antibiotic beads were placed within the hip joint, mainly inferiorly. The beads gravitated to this region as this area was dissected to remove the heterotopic bone and scar tissue from the proximal femur.



Figure 3c: Postoperative AP radiograph taken 3 months after revision surgery. All Calcium Sulfate beads have dissolved. Note no new heterotopic bone has formed. This patient did not receive any perioperative treatment to prevent heterotopic bone formation (i.e., no radiation or Indocin).

Figures 4a - 4f: Radiographs of a 64-year-old male who underwent a two-stage revision protocol for a chronic periprosthetic infection of his right THA. The patient suffers from hypertrophic osteoarthritis and DISH.



Figure 4a: Preoperative AP radiograph of pelvis showing infected right THA. Preoperative aspiration grew Staphylococcus epidermidis. Note endosteal resorption of bone around proximal femoral stem.



Figure 4b: Postoperative radiograph of resection arthroplasty. The hip was stabilized with a Modular Stage One (Biomet, Warsaw, IN) antibiotic loaded methyl methacrylate articulated spacer. 40cc of Stimulan antibiotic beads were placed into the hip joint. Note drain that was placed underneath the tensor fascia layer at closure.



Figure 4c: Preoperative AP radiograph of pelvis prior to reimplantation surgery. This radiograph was taken 8 weeks after resection arthroplasty. All Calcium Sulfate beads have dissolved. Preoperative aspiration of the hip was negative.



Figure 4d: Postoperative AP radiograph of pelvis at reimplantation surgery. The acetabulum was reconstructed with a porous cup cage (Signature Orthopaedics, Chatsville, AU) with screws. A Magnum cup (Biomet, Warsaw, IN) was cemented into the cup cage. A dual articulating bearing was utilized (Biomet, Warsaw, IN). The femur was reimplanted with an Arcos modular stem (Biomet, Warsaw, IN). At closure, 40cc of Stimulan antibiotic beads were placed into the hip joint.



Figure 4e: AP radiograph of pelvis taken 5 weeks after reimplantation surgery. All Calcium Sulfate beads have dissolved. Implants show stable initial fixation.



Figure 4f: AP radiograph of pelvis taken 3.5 months after reimplantation surgery. No heterotopic bone has formed. Implants maintain initial biologic integration.

#### Antibiotic Bead Preparation

This study utilized commercially pure, synthetic neutral pH balanced Calcium Sulfate (Stimulan). The rapid cure kit was used which includes 10cc (20gm) of Calcium Sulfate, 2 premeasured mixing solution bulbs, 1 syringe, 1 pellet mold, and 1 spatula. The mold produces three different sizes for the beads (3, 4.8, and 6mm) as demonstrated in Figure 5 (See Appendices).

For this study, one gram of Vancomycin powder is added to 10cc (20gm) of Calcium Sulfate and the two powders are well mixed. The mixture is then added to 240mg (40mg/ cc) of liquid Tobramycin in a

plastic mixing bowl provided in the kit. Ingredients are mixed for 30 seconds until "doughy." The paste is then applied with a spatula into a silicone bead mold and left to set for 10 to 15 minutes with a typical OR room temperature of 60-62° farenheit.<sup>20,21,22</sup> Once set, the beads are harvested and kept in a sterile container until used.

All patients were followed up for a minimum of 3 months. Failure was recognized as the need for component removal for any reason. Monitoring for infection included clinical exam with C-reactive protein tests at 3 months, 6 months, and one year post-operatively. A suspicion of infection prompted a joint aspiration. For patients undergoing reimplantation procedures, a pre-operative negative culture from joint aspiration was mandatory.

### Results

The volume of Stimulan antibiotic-loaded beads used for each procedure ranged from 5cc to 70cc in hip cases and 5cc to 50cc in knee cases. As early cases showed no significant clinical problems, the volume of Stimulan beads was gradually increased. The upper limit of bead volume was dependant upon the ability to close the deep soft tissue envelope with a tension free closure. The



Figure 5: Photograph showing Stimulan Bead Set. The blue plate is a sterile, silicone mat that can make 3 different sized beads (3, 4.8, and 6mm). In this series we primarily used 3 and 4.8mm beads to increase overall surface area and allow for faster dissolution of Calcium Sulfate. The beads shown here are from a 10cc batch of Stimulan. The smaller beads are 3mm diameter beads. The larger beads are 4.8mm diameter beads.

average volume was different for each of the four different categories and all are listed in Table 1 (see Appendices).

The incidence of wound drainage in this study was relatively low considering the overall complexity of the cases. There were eight cases (3.2%) of postoperative wound drainage requiring intervention. Intervention included lavage and debridement, wound vac placement, and/or application of a compressive dressing on the wound. When the surgical wound began to drain, the postoperative thromboembolic prophylaxis regimen was modified, usually by using mechanical foot pumps, until wound drainage resolved. At the time of debridement surgery, the old Stimulan beads were removed and new beads were inserted into the wound. There were five cases (3.5%) of knee wound drainage, with two cases requiring surgical wound lavage and debridement. There were three cases (2.8%) of hip wound drainage, with two cases requiring surgical wound lavage and debridement.

Heterotopic bone formation was identified in three cases (1.2%). Heterotopic bone formation occurred in one knee case (resection arthroplasty with static spacer) and two hip cases (one resection arthroplasty and one reimplantation procedure).

Heterotopic ossification was seen generally when a large volume of Stimulan was used (average 33cc per case). In all cases, the heterotopic bone was considered mild, rated Brooker I-II class. The character of the heterotopic bone in the two cases that were re-operated (for reimplantation) was considered thin and "wispy." It was easily removed from the surrounding tissues. In review of the postoperative radiographs, the heterotopic bone formed in areas where the Stimulan beads were densely packed.

In two-stage hip and knee procedures, we were able to inspect the surgical wounds at reimplantation. The time between resection and reimplantation ranged from 9 to 15 weeks, with an average of 12 weeks. In all cases, there were no observable beads remaining. In twenty percent of the cases we noticed that the synovium was coated with a thin white layer of material that could not be rubbed away. This white material was typically located within the medial and lateral gutters of knee cases and in the infra-acetabular areas of hips. Transection of synovial specimens showed that the white material was only located on the superficial surface of the synovial tissue. The white coating was generally observed when bead volumes of 20cc or more were used.

Out of our 250 procedures there were 29 complications (11 hips and 18 knees) for a complication rate of 11.6%. All complications are listed in Tables 2 & 3 (see Appendices) along with their MSIS-A host grade. A majority of complications occurred in patients with a grade B or C (MSIS-A) medical host. Eight of the 29 complications had wound related complications (3 hips and 5 knees). There were nine failures (3.6%) in this study. All failures are listed in Tables 4 & 5 along with their medical host grade. Six failures were a result of infection. Excluding the above infection failures, all remaining patients had a normal C-reactive protein when tested between 6 and 12 months post-operatively.

### Discussion

In this series we used Stimulan as a vehicle to deliver a localized dose of antibiotics to an area at risk for infection (i.e. operative wound). This is a preliminary study to gauge the effectiveness

of utilizing this particular carrier in septic and aseptic revision joint arthroplasty of the hip and knee. The strategy of using a localized antibiotic delivery system is that it avoids the potential toxicity of intravenous antibiotics. The side effects of even short courses of IV antibiotics are well documented.<sup>1</sup> Localized delivery via Stimulan into a joint replacement has already been shown to deliver antibiotics up to 50 times greater than MIC levels for many pathogenic bacteria found in orthopaedic infections.<sup>15,16,23,24,33</sup> A local antibiotic delivery system is appealing, as it offers a high local concentration of the antibiotics with low serum levels. In contrast, antibiotic-loaded bone cement (PMMA) has historically been an alternative system used for local antibiotic delivery, but there are problems with this method. Firstly, the antibiotic is released by surface bleaching, not elution. This results in relatively low local drug concentrations.<sup>23</sup> There is also the need for a second surgery to remove the cement beads in single stage procedures. Furthermore, only heat stable antibiotics can be utilized with PMMA. Biodegradable delivery systems are more attractive because they provide solutions for these issues encountered with the PMMA method of antibiotic delivery.<sup>1,2,9,13,28,31,32,46</sup>

Calcium Sulfate has been employed as a bone void filler for a long time and its popularity as a local antibiotic delivery system is growing in the treatment of musculoskeletal infections.7,12,17,29,34,36,37,38 Antibiotic-loaded dissolvable Calcium Sulfate beads have previously been used in clinical trials, but the results have not been favorable. Among the main problems encountered are post-operative wound drainage and a toxic reactive synovitis that occurs when beads are placed within a joint. Wound complication rates were reported to be between 25-30% with several explanations existing for such regular occurrence.<sup>22,3,30,40</sup> The predominant thinking attributes the cause of wound drainage to the purification processes of "traditional" Calcium Sulfate products. Prior to Stimulan, all Calcium Sulfate products were derived from gypsum harvested from the earth. Various proprietary filtering and wash processes were developed to produce medical grade Calcium Sulfate products. Despite arduous attempts to derive pure Calcium Sulfate products, however, impurities still exist.<sup>22,35</sup> Additionally, the chemicals used to wash the

gypsum product still remain within the Calcium Sulfate. The result is that the product, once delivered into the human body, is non-physiologic and potentially inflammatory when exposed to the synovial fluid environment. In contrast, Stimulan is derived from commercially pure, synthetic Calcium Sulfate which is blended via a proprietary process to create a product that is considered less "harsh" to the synovial joint environment. It was for this reason that this study was undertaken.

In our study, the incidence of wound drainage in revision joint arthroplasty was found to be low. Overall 3.2% of cases experienced wound drainage. A majority of the 8 occurrences were found in medically compromised hosts (MSIS-A Grade B or C hosts). Furthermore, wound drainage tended to present in cases where the volume of beads used was  $\geq$  30cc. There are several possible explanations for this occurrence. One explanation is that the large volume of beads caused excessive mechanical stretching of the deep soft tissue envelope with joint range, causing the wound to leak. Another possibility is a chemical effect, as large volumes of beads could potentially cause a hyperosmotic effect resulting in joint distension and wound leakage. A third possible factor is the quality of the local tissues and the health of the patient. In the revision scenario, soft tissues are often attenuated from previous surgery and mechanical damage to the local tissues is commonly encountered. This, combined with poor systemic health (e.g. diabetes, smoking, prednisone treatment), leads to wound drainage. We believe that wound drainage can be mitigated by employing modest bead volumes (<30cc) combined with surgical techniques which encourage a water-tight deep soft tissue envelope.

Heterotopic ossification is another potential concern with the use of Calcium Sulfate as a dissolvable pellet. Calcium Sulfate, when used in the intraosseous environment, is an osteoconductive agent. Its application as a bone void filler is well established.<sup>25,41,44,45</sup> When it is placed within the intra-articular environment, the beads are dissolved within the synovial fluid and eventually resorbed. However, if there is a reduced synovial fluid environment (i.e. arthrofibrosis) and exposed intraarticular bone (from periosteal stripping during surgery) the Calcium Sulfate may have sufficient osteoconductive influence to form new periarticular bone. This is especially so when endoprosthetic hinge devices about the knee are used. Our overall incidence of heterotopic bone in this series was 1.2%. The type of heterotopic bone tended to be thin and laminate. In most cases the heterotopic bone did not dramatically affect joint function. In cases of resection arthroplasty where heterotopic bone formed, it was easily removed at the time of reimplantation. We feel that heterotopic bone formation is not a major prohibitive complication for using commercially pure, synthetic antibioticloaded Calcium Sulfate dissolvable beads.

A potential drawback to using Calcium Sulfate in revision joint arthroplasty is the potential for mechanical abrasion of the prosthetic articular surfaces. The beads within the joint envelope can migrate and get in between the articular surfaces. With weight bearing, the beads can get crushed and can potentially cause scratching of the articular surfaces. Current work is ongoing in 6 retrieval Prostalac spacers to look at the articular surfaces for pitting and scratching (Clarke I, McPherson EJ, Peterson Tribology Laboratory, Loma Linda, CA). Maale et al reported using Stimulan beads loaded with Vancomycin and Tobramycin in singlestage septic revision total knee arthroplasty. They found that the Stimulan beads were soft after hydration and do not scratch the joint surface.<sup>23,24</sup> Even if Calcium Sulfate beads did create scratches or polyethylene pitting, their use for localized antibiotic delivery in periprosthetic infection or total joints at risk for infection still may be preferable. Their use will depend on a case by case risk assessment. Long term clinical follow-up is needed to answer this question more definitively.

In summary, we find the use of commercially pure, synthetic antibiotic-loaded Calcium Sulfate is an acceptable adjuvant treatment tool in revision total hip and total knee arthroplasty. We noted low rates of postoperative wound drainage and heterotopic bone formation. In contrast, prior Calcium Sulfate products derived from processed gypsum have shown significant problems with wound healing and wound drainage.<sup>1,2</sup> The Stimulan-antibiotic construct is adaptable, whereby various antibiotic formulas can be utilized.<sup>3</sup> Furthermore, this localized antibiotic delivery method is relatively inexpensive and obviates the need for a second surgery (i.e. removal of PMMA antibiotic beads).

Initial observations with Stimulan antibiotic beads are encouraging. We will continue to explore and research the efficacy of antibiotic-loaded Stimulan beads. Our next phase is to measure local antibiotic concentrations in-vivo in revision joint arthroplasty. We strive to document and corroborate prior findings by Maale and Eager who showed high local antibiotic concentrations within prosthetic knee cases. Additionally, we will continue to review the mechanical effects that Calcium Sulfate beads have upon the articular surfaces of prosthetic implants. Finally, we would like to conduct a study to examine the potential of improving the results of PJI with Stimulan beads via randomized multicenter trials.

#### Table 1 - Results

Aseptic Revision TKA		Aseptic Revision THA	
N=66		N=58	
Avg Stimulan/case	16cc	Avg Stimulan/case	20cc
Complications	6	Complications	4
Failures	2	Failures	2
Deceased	1	Deceased	1
Drainage	1	Drainage	2
DECRA TKA		DECRA THA	
N=16		N=8	
Avg Stimulan/case	21cc	Avg Stimulan/case	35cc
Complications	1	Complications	1
Failures	2	Failures	1
Deceased	0	Deceased	2
Drainage	0	Drainage	1
Resection TKA		Resection THA	
N=35		N=24	
Avg Stimulan/case	27cc	Avg Stimulan/case	33cc
Complications	7	Complications	4
Failures	0	Failures	1
Deceased	0	Deceased	0
Drainage	2	Drainage	0
Reimplantation TKA		Reimplantation THA	
N=25		N=18	
Avg Stimulan/case	24cc	Avg Stimulan/case	34cc
Complications	4	Complications	2
Failures	0	Failures	1
Deceased	0	Deceased	0
Drainage	2	Drainage	0
-			

Table 2 –	Knee	Complications
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Procedure	Case #	Volume	MSIS-A Host Grade	Complication
Aseptic Knee Revisions	Knee 1	10 cc	В	Dynamic rotational instability with buckling.
	Knee 2	10 cc	В	Wound drainage, cellulitis, periprosthetic infection with wound drainage. I&D with modular bearing exchange. No infection at 2-year follow-up.
	Knee 3	10cc	С	Acute knee infection from dental abscess. Failed DECRA. Implants resected 5 months post-op.
	Knee 4	10cc	А	Arthrofibrosis – knee manipulation.
	Knee 5	20cc	А	Extensor lag.
	Knee 6	10cc	А	Fall with traumatic arthrotomy. I&D and reclosure. No infection at 1-year follow-up.
Aseptic Knee Revisions	Knee 1	10 cc	В	Dynamic rotational instability with buckling.
Aseptic Knee Revisions	Knee 1	10 cc	В	Dynamic rotational instability with buckling.
	Knee 9	20cc	В	Heterotopic bone formation in medial and lateral gutters. Removed at reimplantation.
	Knee 10	50cc	А	Secondary infection with Candida Albicans. Repeat debridement and spacer exchange.
	Knee 11	30cc	А	Wound drainage. Wound vac applied. Drainage resolved.
	Knee 12	30cc	В	Superficial wound dehiscence with drainage. Wound revised and closed.
	Knee 13	40cc	В	Acute renal failure, Creatinine 3.6. No dialysis.
	Knee 14	30cc	В	Acute on chronic renal failure. Dialysis for 3 weeks. Resolved to baseline.
Aseptic Knee Revisions	Knee 1	10 cc	В	Dynamic rotational instability with buckling.
	Knee 16	20cc	С	Wound drainage, I&D. Recurrent infection. AKA.
	Knee 17	30cc	С	Wound drainage at 2 weeks post-op. I&D with lavage. Stable.
	Knee 18	10cc	В	Partial small bowel obstruction. Readmitted at 3 weeks post-op for 5 days. No surgery required.

#### Table 3 – Hip Complications

Procedure	Case #	Volume	MSIS-A Host Grade	Complication
Aseptic Hip Revisions	Hip 1	10cc	В	Wound drainage at 3 weeks post-op. I&D with additional antibiotics beads. Wound infection at 2 months post-op. I&D with antibiotics beads. Stable at 1 year.
	Hip 2	30cc	В	Implant Bow Mismatch. Distal Femoral crack. No additional surgery.
	Hip 3	10cc	В	Hematoma with drainage. I&D with evacuation of the hematoma at 2 weeks post-op.
	Hip 4	10cc	В	Infection. I&D at 4 weeks post-op. Negative aspiration culture at 6 months post-op.
Hip DECRAs	Hip 5	40cc	В	Wound drainage post-op. Malnutrition, albumin 2.1. Recurrent infection at 3 months. Hip Resected at 6 months.
Hip Resections	Hip 6	40cc	A	DVT Rt. Arm from PICC line at 6 weeks post-op. Coumadin therapy.
	Hip 7	40cc	А	Heterotopic bone formation. Removed at reimplantation.
	Hip 8	40cc	В	Heterotopic bone formation. Removed at reimplantation.
	Hip 9	20cc	В	Intra-operative hypotension, sepsis.
Hip Reimplants	Hip 10	40cc	В	Recurrent dislocation. Revision to constrained socket.
	Hip 11	70cc	В	Wound drainage. Clear serous fluid. Wound Vac applied for 5 days.

#### Table 4 – Knee Failures

Procedure	Case #	Volume	MSIS-A Host Grade	Reason for failure
Aseptic Knee Revisions	Knee 20	20cc	В	MRSA infection, extensor allograft removal, lavage debridement. Implant infection free at 1 year.
	Knee 21	20cc	А	Infection -Staph A. Implants resected for 2 stage protocol.
Knee DECRAs	Knee 22	30cc	С	Failed DECRA. Recurrent infection. AKA.
	Knee 23	10cc	В	Recurrent patellar subluxation. VMO Advancement procedure at 4 months. Stable at 1 year. No infection.

#### Table 5 – Hip Failures

Procedure	Case #	Volume	MSIS-A Host Grade	Reason for failure
Aseptic Hip Revisions	Hip 12	10cc	A	Aseptic loosening cup. Revision to triflange cage.
	Hip 13	30cc	А	Aseptic loosening cup. Revision to custom triflange cage.
Hip DECRAs	Hip 14	30cc	С	Recurrent infection. Patient died of concomitant bowel perforation.
				•
Hip Resections	Hip 15	30cc	С	New infection hip at 6 months post-operative. Dental infection Strept Viridans. DECRA. Implant stable at 18 months. Normal CRP.
		1		1
Hip Reimplants	Hip 16	20cc	С	Reinfection at 3 months. DECRA procedure. Patient with CLL. Died from blast crisis 6 months after DECRA procedure.

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### Surface roughness of retrieved femoral heads in CoCr-Polyethylene Hip Bearings – A retrieval assessment with 11-17 years follow-up

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### Introduction

Metal-on-polyethylene (MPE) bearings have been the gold standard in total hip arthroplasty (THA) for over 40 years. However, even for the improved polyethylenes steadily gathering a reputation of very high wear resistance, it also clear that there are additional issues to consider (Fig. 1). It is well documented that impingement of metalon-polyethylene (MPE) is a serious risk that can damage the polyethylene liner, produce additional wear debris and also lead to 3rd-body abrasion and roughening of the femoral head.<sup>1-3</sup> Adding to these risks is the contemporary use of larger femoral heads with the consequence of adjusting to thinner polyethylene liners once believed to be a contraindication in cup design.<sup>4</sup> The superior surface finish of CoCr implants mated with polyethylene bearings is believed to be one factor in the longevity of metal-on-polyethylene bearings (MPE). However, it may be that under long-term conditions in vivo, these 3rd body-wear particles eventually degrade the MPE surfaces.<sup>2,5-7</sup>

The two-body and three-body wear mechanisms associated with MPE is an unavoidable risk given the nature of the hip mechanics. Studies of cup impingement have documented an incidence ranging 45-68%. However in MOM studies, impingement evidence has climbed to 96%.<sup>8</sup> We therefore sought evidence of roughening damage to the femoral heads as a result of 3rd-body wear. A study of MPE retrievals with average 12-years



Fig. 1 Introduction to the risks of the different modes of debris production: i) neck-to-cup impingement wear, ii) head pressure on contre-coupe rim of liner14, iii) backside wear by pistoning liner, iv) bead shedding, v) metal debris shed from taper junction, vi) metal debris emitted by femoral-stem construct and vii) micro-separation and subluxation wear.

follow-up (N = 35 cases)<sup>9</sup> described CoCr roughness averaging 62nm (Ra= 41-80nm). A subsequent retrieval study (N=43: 6-years) with half the follow-up time described much lower roughness of 10nm (Ra), with roughness for non-worn surfaces reported as low as 3nm.<sup>10</sup>

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The 1st goal of this study was determine if femoral heads became rougher or smoother in MPE bearings with time (10-20 years). The 2nd goal was to determine if CoCr roughness simulated in laboratory tests was an adequate representation of that occurring in-vivo.







b) View-2

### Methods

The MOM cases were performed by various surgeons and revised in the Orthopedic Dept. of Loma Linda University. The analytical studies were conducted in the DARF Retrieval Center. Six CoCr femoral heads were chosen with 11-17 years duration. Except for one 26mm head, all were 28mm and mated with non-cemented, metal-backed acetabular shells with conventional polyethylene liners. All studies conducted at DARF Center were of a non-destructive nature for loaned MOM. Implants were scrutinized for any impingement damage and liners mounted on heads to check geometry of any damage sites. Implant 3D-geometry was studied by CMM, wear patterns were imaged by SEM and energy dispersive spectroscopy (EDS). Surface roughness was analyzed by white-light interferometry (WLI).

Unique to the DARF Center, the first step in the analysis was to determine which areas the patient habitually walked on in the head and cup. Here the main-wear zones (Fig. 1: MWZ) were uniquely defined as "normal". Accordingly, the remaining areas were defined as non-wear zones (NWZ) and these were also studied for clues to "abnormal" wear damage. These areas were mapped visually and optically on each femoral head and cup. Surface roughness was assessed by interferometry (Newview 600, Zygo Inc) for both MWZ (12 data points) and NWZ areas (6 data points). Care was taken to exclude areas of protein contamination



Fig. 3 Mapping of MWZs on MPE



Fig. 4. SEM imaging CoCr

from such roughness surveys.<sup>8,11</sup> In addition, any abnormal wear damage of a local nature was excluded from such roughness surveys and profiled separately in greater detail. SEM imaging was used to confirm wear topography (MA 15, Zeiss Inc) and any metal contamination (EDS, Bruker Inc). The extent of the surface areas was then determined using standard spherical algorithms and their locations marked for additional microscopic analyses (Fig. 1).

### Results

After 11 to 17 years duration (Table 1: average 13 years), the MWZ on femoral heads covered 292-774mm<sup>2</sup> in area (Table 2: average = 558mm2), representing a x2.7-fold variation. Relating these MWZ areas to the hemispherical surface area of the head, these patients had walked on 24-63% of the available surface area (45% on average). SEM imaging revealed the typical carbide pattern (size < 10µm), small pits and fine micron-size,



Fig. 5. SEM imaging typical CoCr head.



Fig. 6. SEM imaging "worst case" CoCr head.

Explant #	Manufacturer	Reason for Revision	F/U (yrs)	MWZ area	MWZ %	MWZ Ra (nm)	NWZ Ra (nm)	MWZ/ NWZ
1 (44F)	Zimmer	osteolysis	17	699	56	11	6	1.8
2 (58F)	IOI	osteolysis	15	391	32	11	6	1.8
3 (67F)	BC	cup migration	12	634	51	8	4	2.0
4 (83M)	Zimmer	osteolysis	12	774	63	10	5	2.0
5 (91F)	DePuy	osteolysis	11	557	45	13	6	2.2
6 (59M)	DePuy	osteolysis	11	292	24	10	4	2.5
Averages (n=6)			13	558	45	10.5	5.2	2.0

Table 1 MPE explants with patient demographics



Fig. 7. Comparison of published surface roughness studies (ranking system redrawn from study by Sorimachi et all).

surface scratches. There was no evidence of the large microgrooves (>  $40\mu m$  width, >  $0.5\mu m$  depth) commonly identified on MOM retrievals.

The surface roughness of the MWZ areas appeared exceedingly smooth at 8-13nm (Ra = 11 average roughness)and only slightly larger than the range 4-6nm for the NWZ (average Ra = 5nm). Individual profiles of such worn surfaces showed peaks and valleys within  $\pm 10$ nm range and occasional scratches penetrating 30nm into the CoCr surface (Fig. 5). Representing the 'worst case' scenario in this study, some areas revealed scratches with peaks and valleys within the  $\pm 30$ nm range, some as wide as 20um (Fig. 6).

### Discussion

Micro-imaging revealed that femoral surfaces in these MPE bearings appeared excellent even with 11-17 years of use in vivo. The appearance of

the micron-size pits and fine surface scratches on these CoCr bearings were typical of 3rd-body abrasion created by release of small surface carbides. Totally absent in this MPE study were the micro-grooves created in MOM bearings by large CoCr particles acting as third-body abrasives.<sup>8</sup> The latter phenomenon are believed to be a consequence of impingement between femoral necks and exposed CoCr liners.<sup>8,12</sup> Thus our study illustrated that CoCr femoral head surfaces used with polyethylene liners may become only slightly rougher with long-term implantation. These data were therefore supportive of a previous retrieval study with a mean follow-up of 7 years.<sup>10</sup> It was noted that such roughness grades

remained well below the ASTM guideline<sup>13</sup> for even a new THA bearing (Fig. 7: Ra = 50nm). Therefore, our conclusion was that this level of CoCr roughness could not be a contributor to long-term wear and osteolysis in these patients with mteal-onplyethylene bearings.

The mapping of habitual wear areas on the CoCr heads revealed that MPE patients walked on an average of 45% of the femoral head hemisphere. In MOM bearings, the area of habitual wear was noted to be slightly larger at 55% of the hemisphere.<sup>8</sup> These new MPE data indicated that the patients walked similarly on MPE and MOM bearings, despite the fact that the cups represent remarkably different hardness and contact mechanics.<sup>8</sup> The design preference for the American surgeon is to use a polyethylene liner inside a metal acetabularshell ('press-fit' cup). Thus the protective polyethylene cup rim may be of considerable benefit if impingement and subluxation presents.<sup>14</sup>

### **Significance and Conclusions**

- Our study showed the surface finish of 28mm CoCr femoral heads (Ra < 15nm) used in combination with polyethylene liners can remain excellent into the 2nd decade of use.
- 2. With modular metal shells there is the added risk of cup-impingement and possible damage to the polyethylene liner. However we found no evidence of the large microgrooves typically produced in MOM bearings by circulating metal particulates, i.e. 3rd-body abrasion.
- 3. The wear area assessments showed that these patients walked on their MPE bearings in a very similar way to patients with MOM bearings.

Explant #	F/U (yrs)	MWZ area (mm2)	MWZ %Hemi	MWZ Ra (nm)	NWZ Ra (nm)	MWZ/ NWZ
Ratio						
1 (44F)	17	699	56	11	6	1.8
2 (58F)	15	391	32	11	6	1.8
3 (67F)	12	634	51	8	4	2.0
4 (83M)	12	774	63	10	5	2.0
5 (91F)	11	557	45	13	6	2.2
6 (59M)	11	292	24	10	4	2.5
Mean (n=6)	13	558	45	11	5	2.0

Table 2: Summary of MWZ area calculations and head roughness (Ra) data (note 1,000nm = 1micron)

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### A Transcutaneous Intramedullary Attachment For AKA Prostheses

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### Introduction

Achieving good functional results for ambulatory amputees with above-knee amputation (AKA) can be challenging. Patients) often experience poor socket fit exacerbated by minor weight changes, sweating, and skin problems. There have been several attempts at transcutaneous intramedullary fixation with good results. Several investigators have had success since the late 1990's with a number of patients undergoing percutaneous, osteointegrated prosthesis implantation. Contemporary strategies include a transcutaneous,



Figure 1. A transcutaneous, press-fit distal femoral intramedullary device whose distal external aspect serves as a hard point for AKA prosthesis attachment

press-fit distal femoral intramedullary device whose distal external aspect serves as a hard point for AKA prosthesis attachment (Figure 1). Typically the implant is placed in retrograde fashion as a first stage, followed approximately 6 to 8 weeks later by stomatization in which the distal aspect of the implant is exposed and an extension added for fixation of the AKA prosthesis. Indications for surgery typically are persistent AKA prosthesis socket difficulties with a history of AKA following trauma or tumor.

### Background

Most investigators credit Branemark in Sweden with the idea of a percutaneous, osteointegrated prosthesis which has been successful in dental implantation. In 1997, R. Branemark reported on the first femoral intramedullary percutaneous device using a 12 cm screw-type device for a patient with an above-knee amputation. In 1999, ESKA produced the Endo-Exo Femurprosthesis (EEFP) which was first implanted into the femoral canal of a young motorcyclist who lost his leg in an accident and subsequently used for a number of patients in Germany. There have been variations in the design, including some types to allow proximal fixation to other devices such as a hip replacement, but commonly the device is a modular, noncemented device that fits within the intramedullary canal of the femur and has a hardpoint attachment that exits through the skin (Figure 2).

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Figure 2. The device is a porous modular construct with the smoothly polished coupler distally exiting through the skin.

### Challenges

Stable fixation and prevention of deep infection are the principal challenges with a transcutaneous femoral prosthesis of this type. First, a bone guided, soft tissue penetrating femur prosthesis has to have secure and durable fixation of the shaft of the prosthesis in the intramedullary canal of the femur; loading moments and stresses can be significant. Second, the dermal interface must heal adequately to allow functional activity and activities of daily living (including submersion) without significant persistent risk of infection.

Stable fixation can be achieved in several ways; the German device utilized a spongiosa surface of casted cobalt chrome that allows for a porous surface for bone ingrowth. This surface has been utilized on a number of different hip prostheses with good results as well. Other alternatives may include plasma sprayed titanium surfaces or HA coating.

Aschoff achieved good results and few issues with infection by breaking the procedure down into 2 stages, with the first stage comprised of a primary, closed procedure with the stump closed over the implanted prosthesis. Six to eight weeks later, the stoma is created with a second procedure, allowing the stump to heal with a solid seal around the prosthesis after tissue swelling has subsided.

### **Surgical Considerations**

Preoperative planning requires consideration of the local stump, including scars or burns as well as radiographic determination of the length and diameter of the prosthesis. A CT scan is helpful for determining the necessary implant size and limb length. Typically at least 12 to 15 cm of femoral shaft is needed for stable fixation.

To minimize stump difficulties and soft tissue problems, the procedure is divided into 2 separate surgeries, which allows for the swelling and fluid fashion (similar to a retrograde femoral nail). A tight press-fit is achieved with the metal surface of the intramedullary component. The stump may also be debulked or scars can be revised at this point, and the stump is closed over the capped prosthesis.

accumulation in the stump to subside dramatically after the initial implantation. The first stage involves reaming the femoral

canal in a retrograde

The second stage is typically an outpatient procedure, essentially using a "cookie-cutter" to sharply cut an opening in the skin and soft tissue over the stump for the coupler. Approximately 6 to 8 weeks after the primary procedure with implantation of the endoprosthesis - assuming good healing of the wound and stump - the second procedure is performed to create the stoma and attach the transdermal coupler (Figure 3). The sharp cutter is passed percutaneously over the guide,



Figure 3. The device is coupled to a leg prosthesis, with a very functional transfer of the load across the prosthesis to the femur.

producing an intentionally larger diameter circular skin incision than the coupler diameter. The coupler connects to a prosthetic leg, and essentially any type of external prosthesis may be used. After the second procedure, the skin starts to scar down around the coupler. The skin will epithelialize around the stoma channel from the outer skin margin and connective tissue will fill in down to the femoral cortex, similar to a dental implant. Partial weight bearing can begin as early as 2 to 3 weeks after the stoma procedure. Full weight bearing and a secure gait can be achieved 4 to 6 weeks after the stoma procedure.

### **Future Directions**

The devices in recent years have all included a smoothly polished coupler that replaced the initial rough surface couplers. Early designs used a porous surface for the transdermal coupler, but hypergranulation tissue sometimes appeared that was uncomfortable and occasionally necessitated soft tissue debridement procedures. In these cases, replacing the coupler with a smoothly polished surface resolved these issues and dramatically diminished soft tissue problems and minor superficial infections. Additionally, early stoma procedures were the same or slightly smaller diameter than the coupler. Aschoff reported that changing the stoma procedure now allows for sharply dissecting a slightly larger diameter than by changing from a casted cobalt chrome intramedullary device to a titanium porous coated, plasma sprayed, or HA coated device.

### Conclusion

The concept of using a transcutaneous intramedullary device for patients for whom a traditional socket type AKA prosthesis presents difficulties may be a benefit to many amputation patients. It is especially promising for active, healthy, post-traumatic amputees and may lead to fewer costly socket refittings and increased comfort. Additionally, it may also contribute to improved gait and comparatively less energy consumption by more efficiently transmitting the load directly to the skeletal frame.

Soft tissue problems at the stoma can be an issue, but recent investigators have reported improved results with modifications to the technique, particularly use of a smoothly polished coupler and larger circular incision and a two stage procedure. Future design changes, particularly in materials and by using more modern fixation techniques learned in hip arthroplasty evolution, may also improve the outcomes and durability of the procedure.

the implant, which promotes epithelialization. Some patients have returned to activities they previously could not do, such as diving and swimming.

Future directions include use of the endoexo technique for tibial and humeral amputees. Additionally, the designs could possibly be improved from an engineering perspective





### Revision of Hip Resurfacing Arthroplasty to Neck Sparing "ARC" Total Hip Arthroplasty

John Keggi, MD<sup>†</sup>

A CASE REPORT

### Introduction

Modern hip resurfacing arthroplasty (HRA) with a metal-on-metal articulation has attracted many patients worldwide over the last 15 years for the potential benefits of high activity level and bone preservation. Good mid-term results are reported, especially in male patients. However, there is now a need for revision options for a subset of patients who will require early revision for unanticipated adverse local tissue reaction (ALTR) associated with the metal-on-metal articulation. We present a case of HRA conversion to total hip arthroplasty (THA) using a neck-sparing THA component.

### **Case Report**

A 42 year old male initially presented to an outside institution with a one year history of progressive right hip pain, right hip stiffness and irritability on exam and radiographs showing degenerative changes of the right hip. He had inadequate relief with non-operative measures and subsequently underwent uncomplicated right hip resurfacing in 2008. He initially had good relief of pain and returned to an activity level that included heavy lifting and manual work. In 2010 he began to experience right groin pain and hip achiness with high levels of activity. AP and lateral radiographs showed no loosening, osteolysis, fracture or avascular necrosis at routine follow up. Cobalt blood levels were obtained serially. Levels were initially reported at 10-11 micrograms/liter and subsequently were rising to the range of 19-23 micrograms/liter. Metal artifact reduction sequence MRI was obtained in June 2011 and was interpreted as showing wear-induced synovitis and distension

of the pseudocapsule with fluid collection but no overt tissue destruction.

Upon subsequent presentation to our facility later in 2011 he reported extremely severe and constant pain in the right hip. His gait was notable for a mild limp, right hip irritability and stiffness. AP and lateral radiographs of the right hip showed wellfixed resurfacing components and no osteolysis. Cup abduction angle was 43 degrees on AP film. Anteversion was measured at 32 degrees on crosstable lateral radiograph. (Figure 1 a-c)

In September 2011 he elected to proceed with right hip revision arthroplasty in light of increasing hip pain, rising metal ion levels and MRI evidence of fluid collection with synovitis. Revision was accomplished using a direct anterior approach. Intra-operative findings included well-fixed components, a large fluid collection, posterior impingement of the femoral neck on the acetabular component and psoas tendon tightness/atenuation over the components anteriorly. The femoral neck was osteotomized at the base of the resurfacing component with easy component extraction. The resurfacing acetabular component was removed with minimal bone loss and without complication. A 60 millimeter, multihole ingrowth shell was placed with 3 screws. The femoral side was reconstructed with a neck-sparing, modular stem. An alumina ceramic-on-ceramic bearing was used. Culture of the fluid was negative for infection.

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Figure 1a. AP radiograph right hip HRA



Figure 1b. LCross table lateral radiograph right hip HRA



Figure 1c. Frog lateral radiograph right hip HRA



Figure 2a. Post-op AP radiograph

Figure 2b. Post-op lateral radiograph

Figure 2c. One year post-op AP radiograph



### Discussion

Many patients and surgeons have favored HRA in the last 15 years for the benefit of bone preservation. Young patients, especially, have elected HRA with the idea that they would have more proximal femur in the case of revision and that revision to THA could be accomplished with primary THA components when, after many years, their HRA had failed. With greater understanding of HRA designs, metallurgy, component positioning variables, local soft tissue reactions, and the market recall of a HRA system, surgeons are faced with a group of young patients requiring revision of HRA to THA. Bone preservation is still a vital interest of theirs even if HRA revision is required. A neck-sparing THA design can accomplish the goals of removing the MOM bearing, providing an alternative advanced or standard bearing and preserving femoral neck bone for later reconstruction.

In our case the neck osteotomy was performed immediately at the base of the HRA femoral component. Preparation of the femur was identical to that of a primary THA with this device. No additional bone resection was required and the option of future reconstruction with a standard primary THA device was retained. Proximal femoral offset and leg length were properly reconstructed and the implant shows good integration at one-year follow up. (Figure 2 a-c)

### Conclusion

A neck-sparing femoral implant can be easily employed in HRA revision to THA thereby retaining the HRA benefit of bone preservation that is vital to younger patients.

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### **JISRF Editorial Comments**

by Timothy McTighe, Dr. H.S. (hc) • Executive Director, JISRF & Editor-in-Chief of Reconstructive Review

### "Kransk ASR<sup>®</sup> Jury Award"

I believe we have the best of all world opportunities here in the United States but there are times when I wonder about our justice system. The Kransk ASR judicial hearing has highlighted the recent problems of metal-on-metal bearings.<sup>1</sup> Wear generated debris from bearings of total hip arthroplasties and resurfacing arthroplasties can cause considerable tissue destruction and bone necrosis causing longterm patient disability. The metal ions may also be disseminated systemically within the patient's body.

The recent decision of the jury to award \$8,338,000 in compensation damages for a revised ASR metalon-metal bearing hip seems to be excessively punitive, even though the jury found that DePuy adequately warned of the risks associated with their use of this device. Kransky's lawyers had asked jurors for \$338,000 in economic damages, \$5 million in economic damages for pain and suffering, and up to \$179 million in punitive damages. No punitive damages were awarded, so it is reasonable to question the additional \$3 million beyond the asking compensation for pain and suffering.

Since the jury awarded higher than requested compensation for pain and suffering one has to ask was this decision the act of an overly sympathetic jury especially in light of a comment made by a juror after the verdict "I wanted punitive damages."<sup>1</sup>

Elective surgery is not without inherent risks. The question of who is ultimately accountable for a failed surgery that requires replacement surgery of a potentially deficient implant remains an open debate. Should the surgeon be held responsible as he is the final decision maker on which type of implant he will use in the patient's best interest? Should the hospital have an active role in the implant choice and what of the insurance company who is the payer for the device and the surgical procedure? The FDA is the august body which regulates the use of devices and allows the implant to be sold on the market and used to improve patients' hip pain and function once they have been deemed to be effective and safe for use in patients.

In addition lets not forget the patient who electively decides on surgery and may not follow surgeon instructions on related physical activities.



There is no single decision maker who justifiably is solely responsible in this process.

What role should our legal system play when we (the orthopedic community) make honest mistakes when striving to advance technology that has the potential to benefit patients? Problems with a variety of bearing materials have arisen. Some are specifically related to the material properties, others to the design of the implant as well as surgical error. In my opinion this is an industry that has taken care to self-regulate and is aided by the Continuing Medical Education (CME) system. As we are about to begin the 2013 American Academy of Orthopedic Surgeons Annual Meeting in Chicago IL, we will see papers and lectures on design and technical problems associated with total joint surgery. All delegates attend to learn and stay current in an everchanging environment. Why? So they can provide the best possible care for their patients.

The legal argument against the ASR hip system was that the design was defective. Have we seen poorly designed devices that have come to market? No designer, bioengineer, or product company knowingly marketed a design deficient implant. It is extremely difficult to anticipate all the potential failure modes that can affect the performance of a new device. In my 42 years as a member of the orthopedic community and as a designer of total joints (14 patents), I am well aware of the burden of trying to anticipate failure modes, while at the same time striving to advance patient outcomes. The benefit of hindsight is a luxury.

Regrettably it is the patient that bears the brunt of a flawed implant and they should be properly compensated for their pain, loss, and possible permanent curtailment of their chosen lifestyle. In this particular case the restive process of preventing the jury from hearing testimonies may have been critical to the final conclusion of the hearings. The jury did not have the benefit of the details about the FDA's review in the evaluation and clearance of the ASR device. Why would such a critical part of the process of the analysis of a new device be denied to the jurors? We are aware that to bring a new device to market there remains a rigorous process in place before any product can be sold or implanted.

It is my understanding that DePuy will appeal. I am not suggesting that DePuy should not be held liable, but it would be in the best interests of all parties concerned that all the facts be argued and debated in the courts. Only then can the merits of this case be fully appreciated and decisions rendered.

What have we, the orthopedic community, learned from the recent legal arguments? We should note that implant manufacturers involved in patient care should uphold the highest quality and integrity not only in device testing, but also in post-market evaluation of their products. Is the FDA 510K pathway (of a substantive equivalent) adequate given that minor alterations of device design may radically alter the clinical outcome? Perhaps there should be a controlled exposure of a new device into the market to allow for the careful monitoring of failures of any device over time. To this end, I have discussed this verdict with legal healthcare experts who have agreed with my observations and opinions. However, this Editorial Comment is made by me and does not represent the opinion of the Reconstructive Review Editorial Board or the Board of Trustees, or Clinical Surgical Advisors for The Joint Implant Surgery & Research Foundation.

### Compensatory Damages<sup>2</sup>

Compensatory damages provide a plaintiff with the monetary amount necessary to replace what was lost, and nothing more. In order to be awarded compensatory damages, the plaintiff must prove that he or she has suffered a legally recognizable harm that is compensable by a certain amount of money that can be objectively determined by a judge or jury.

### Punitive Damages<sup>3</sup>

Monetary compensation awarded to an injured party that goes beyond that which is necessary to compensate the individual for losses and that is intended to punish the wrongdoer.

#### **Reference:**

- 1. Orthopaedics This Week Monday, March 11, 2013
- 2. http://legal-dictionary.thefreedictionary.com/Compensatory+Damages
- 3. http://legal-dictionary.thefreedictionary.com/punitive+damages

requirement for a national joint registry. We all understand and appreciate that it remains a privilege to care for patients and that we are all accountable.

there is a real

It appears to me that the jury may have put punitive damages in a compensatory verdict and the court should consider using its power to reduce it to the reasonable amount.



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### CME COURSES

#### ICJR/MAOA Current Concepts in Hip Disorders

April 17, 2013 Amelia Island, FL www.maoa.org

#### Philadelphia Revision Course

April 26 – 27, 2013 Philadelphia, PA icjr.net/2013philadelphia

#### ICJR South May 9 – 11, 2013 Charleston, SC icjr.net/2013charleston

Marshall University Arthroplasty Course May 16 – 18, 2013 White Sulphur Springs, WV icjr.net/2013westvirginia ICJR West June 6 – 8, 2013 Napa, CA icjr.net/2013napa

#### **CAOS Orlando 2013** June 12 – 15, 2013 Orlando,, FL caos-orlando2013.com

Modern Trends in Joint Replacement (MTJR) September 19 – 21, 2013 Palm Springs, CA icjr.net/2013palmsprings

Anterior Hip Course September 26 – 28, 2013 Houston, TX icjr.net/2013houston

#### Perspectives in Joint Arthroplasty

October 11 – 12, 2013 Fall River, KS icjr.net/2013flintoak

#### Las Vegas Shoulder Course November 14 – 16, 2013 Las Vegas, NV icjr.net/2013lasvegas

Winter Hip & Knee Course January 16 - 19, 2014 Vail, CO icir.net/2014vail

### ICJR GLOBAL CONGRESSES



#### ICJR East (combined 14th Annual ISK and EKA Conference)

October 4 – 6, 2013 • New York, New York icjr.net/2013newyork

Over the years, the Insall Scott Kelly Course has enhanced its curriculum, which is focused on sports medicine as it relates to the knee and shoulder and hip and knee reconstruction, by incorporating live surgeries, case reviews, scientific posters, and more opportunities for surgeon-to-surgeon interaction. While maintaining an intimate setting, this course has also increased significantly in attendance and has expanded its reach globally. Our 2013 course promises to be better than ever as we are combining our efforts with the European Knee Associates to bring to you a truly global congress.

COURSE CHAIRMEN: Jean-Noël Argenson, MD, Aix-Marseille University Hospital Sainte-Marguerite • W. Norman Scott, MD, FACS, Insall Scott Kelly Institute for Orthopedics and Sports Medicine • Giles R Scuderi, MD, Insall Scott Kelly Institute for Orthopedics and Sports Medicine



#### Pan Pacific Orthopaedic Congress

July 16 – 19, 2014 • Kona, Hawaii icjr.net/2014hawaii

The 2014 ICJR Pan Pacific Congress will bring together over 1,000 surgeons and researchers from the Pacific Rim and North America to expand our global understanding of key issues in orthopaedics. With a comprehensive focus on knee, hip, shoulder, elbow, and ankle reconstruction, as well as sports medicine, this course will explore the areas of customized instrumentation, surgical navigation, imaging, clinical evaluations and outcomes, and long-term follow-up with a goal of translating research into practical medicine and better patient care.

COURSE CHAIRMEN: Douglas A. Dennis, MD, Colorado Joint Replacement • Arlen D. Hanssen, MD, Mayo Clinic • Richard D. Komistek, PhD, University of Tennessee • W. Norman Scott, MD, FACS, Insall Scott Kelly Institute for Orthopedics and Sports Medicine

#### World Arthroplasty Congress



April 16 – 18, 2015 • Paris, France icjr.net/2015paris

The World Arthroplasty Congress is the first-ever meeting dedicated to the exchange of surgical innovation, cutting-edge science, and practical knowledge related to joint reconstruction on a global scale. While societal, political, and economic climates, as well as surgical environments, may vary drastically from one country to the next this congress aims to put aside these differences and so we can learn from one another with a common goal of advancing the field of reconstruction and improving patient care.

COURSE CHAIRMEN: Jean-Noël Argenson, MD, Aix-Marseille University Hospital Sainte-Marguerite • Arlen D. Hanssen, MD, Mayo Clinic • W. Norman Scott, MD, FACS, Insall Scott Kelly Institute for Orthopedics and Sports Medicine • Jan Victor, MD, PhD, AZ St. Lucas Hospital, Brugge



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