Patients First
Quality counts when referring patients to hospitals and physicians, so Cleveland Clinic has created a series of Outcomes books similar to this one for many of its institutes. Designed for a healthcare provider audience, the Outcomes books contain a summary of our surgical and medical trends and approaches, data on patient volume and outcomes, and a review of new technologies and innovations.

Although we are unable to report all outcomes for all treatments provided at Cleveland Clinic — omission of outcomes for a particular treatment does not mean we necessarily do not offer that treatment — our goal is to increase outcomes reporting each year. When outcomes for a specific treatment are unavailable, we often report process measures that have documented relationships with improved outcomes. When process measures are unavailable, we report volume measures; a volume/outcome relationship has been demonstrated for many treatments, particularly those involving surgical technique.

Cleveland Clinic also supports transparent public reporting of healthcare quality data and participates in the following public reporting initiatives:

- Joint Commission Performance Measurement Initiative (www.qualitycheck.org)
- Centers for Medicare and Medicaid (CMS) Hospital Compare (www.hospitalcompare.hhs.gov)
- Leapfrog Group (www.leapfroggroup.org)
- Ohio Department of Health Service Reporting (www.odh.state.oh.us)

Our commitment to providing accurate, timely information about patient care is designed to help patients and referring physicians make informed healthcare decisions. We hope you find these data valuable. To view all our Outcomes books, visit Cleveland Clinic's Quality and Patient Safety website at clevelandclinic.org/quality/outcomes.
Dear Colleague:

I am proud to present the 2007 Cleveland Clinic Outcomes books. These books provide information on results, volumes and innovations related to Cleveland Clinic care. The books are designed to help you and your patients make informed decisions about treatments and referrals.

Over the past year, we enhanced our ability to measure outcomes by reorganizing our clinical services into patient-centered institutes. Each institute combines all the specialties and support services associated with a specific disease or organ system under a single leadership at a single site. Institutes promote collaboration, encourage innovation and improve patient experience. They make it easier to benchmark and collect outcomes, as well as implement data-driven changes.

Measuring and reporting outcomes reinforces our commitment to enhancing care and achieving excellence for our patients and referring physicians. With the institutes model in place, we anticipate greater transparency and more comprehensive outcomes reporting.

Thank you for your interest in Cleveland Clinic's Outcomes books. I hope you will continue to find them useful.

Sincerely,

Delos M. Cosgrove, MD
CEO and President
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Chairman’s Letter

The 2007 Orthopaedic and Rheumatologic Institute Outcomes book is the work product of many clinicians and clinical research staff. Over the last three years, we have expanded our capability to collect clinical outcome data on all surgical patients being treated on our main campus and have started to collect this same data at all of our clinical care sites within Northeast Ohio. In 2008, we will begin data collection for surgical patients being treated at our Florida Hospital in Westin.

Our Orthopaedic Surgery Department has used a standardized minimum data set that consists of the SF12 and a Musculoskeletal Quality of Life outcome tool. In addition, we utilize a joint specific outcome tool for all patients with hip, knee and shoulder surgery. We are expanding this in 2008 to include foot and ankle and pediatric conditions. All data is collected as part of the standard patient clinic visit before and after surgical treatment. Data is analyzed for all patients based upon the type of procedure performed for a specified length of follow-up that is considered to be clinically relevant to the type of surgery performed. In this publication we present data for total hip, knee and shoulder arthroplasty. We present outcome data for ACL reconstruction, rotator cuff repair, hip arthroscopy and arthroscopic meniscectomy. We also report clinical volume data, preoperative antibiotic administration, re-admission rates within 30 days of discharge, infection rates and patient satisfaction data.

Our Rheumatology Department is a leader in the evaluation and treatment of connective tissue diseases, including vasculitis, autoinflammatory diseases, metabolic bone diseases and scleroderma, and coordination of care with cardiovascular medicine, orthopaedics, pathology, imaging and surgery. The Vasculitis Center is conducting studies of novel treatment protocols utilizing randomized clinical trials. The Fasenmeyer Center for Clinical Immunology has promoted innovative research in vasculitis and viral-associated immune disorders, education and training for clinical immunology, and community outreach and awareness of public health issues. The Center for Osteoporosis and Metabolic Bone Diseases is evaluating novel biologic and anabolic therapy for osteoporosis. The Section of Pediatric Rheumatology has started a combined fellowship program with Case Western Reserve University’s rheumatology program, and established links with the NIH and the Autoinflammatory Disease Clinic. Cardiovascular outcomes in patients with rheumatic diseases is an ongoing focus of research. This year's Outcomes book highlights the clinical outcomes of patients with osteoporosis, inflammatory arthritis, Wegeners granulomatosis and giant cell arteritis.

Joseph P. Iannotti, MD, PhD
Orthopaedic and Rheumatologic Institute
Institute Overview

The mission of the Orthopaedic and Rheumatologic Institute is to provide world-class, compassionate care and world-class service to all patients seeking treatment at Cleveland Clinic. Serving patients is our first and most important priority. We provide care for patients with the most complex clinical problems from around the country and the world. Our Institute is dedicated to the education and training of our residents and fellows as well as our colleagues both within and outside of Cleveland Clinic. Our goal is to select and train individuals interested in remaining academically productive so that they contribute back to our profession through their own teaching and research. Our Institute is also dedicated to the development of new knowledge and innovation through both basic science and clinical research activities. Our current full-time faculty includes 42 orthopaedic surgeons (37 orthopaedic + 5 spine), 29 rheumatologists, 12 musculoskeletal radiologists, 6 podiatrists, 9 office-based sports medicine physicians, 2 doctoral-level research staff and 10 basic science research staff members with secondary appointments in our Orthopaedic Surgery Department.

The 2007 Outcomes book reflects our growing emphasis and effort to measure the functional outcome of a wide range of surgical procedures and non-surgical treatments performed by the faculty in our Institute. This publication reflects the surgical care of patient treated on the main campus and at our outpatient surgical centers by the Orthopaedic Surgery Department. Our Rheumatology Department cares for patients with systemic immunologic diseases resulting in vasculitis and inflammatory arthritis. We provide in this publication the outcomes of care for these patients.

Our focus this year is on hip, knee and shoulder arthroplasty, and ACL and rotator cuff repair. This publication reports, for these procedures, a minimum of one year follow-up. We have used validated functional outcome tools that use patient reported data (SF-36, SF-12 PENN Shoulder Score and KOOS scores). We also report, for many commonly performed procedures, the effect of patient-reported comorbidity on the severity of the preoperative disability and the effect of these comorbidities on the short-term functional outcome after surgery. We also report our patient satisfaction, length of stay and readmission data for several commonly performed procedures. We have correlated these parameters of the treatment process with patient-reported comorbidity at the time of index surgery.

Our Institute’s Center for Clinical Outcomes and Center for Vasculitis Research include 11 research staff and 4 part-time support staff. This group manages 31 prospective research projects, 52 clinical databases and 24 clinical trials in many areas of orthopaedic surgery and rheumatology. These centers are responsible for the collection, management and analysis of the data presented in this year’s Outcomes book. Our staff will continue to expand our department’s efforts in the next year to include clinical outcome data collection for other outpatient and inpatient clinical care sites within the Cleveland Clinic health system. We also will add other database registries for other subspecialty areas of orthopaedic surgery. We hope you find the 2007 publication informative and of even greater value than the 2006 publication; and we look forward to your comments and feedback.
2007 Statistics

Number of Surgeries in 2007

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
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<tbody>
<tr>
<td>Spine (Orthopaedic Department)</td>
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</tr>
<tr>
<td>Lower Extremity</td>
<td>7,555</td>
</tr>
<tr>
<td>Upper Extremity</td>
<td>4,158</td>
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<tr>
<td>Other</td>
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Number of Upper Extremity Surgeries in 2007

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<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand</td>
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<tr>
<td>Forearm</td>
<td>1,107</td>
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<tr>
<td>Humerus</td>
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<tr>
<td>Shoulder</td>
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Number of Lower Extremity Surgeries in 2007

<table>
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<tr>
<th>Category</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Foot and Toes</td>
<td>805</td>
</tr>
<tr>
<td>Leg and Ankle Joint</td>
<td>631</td>
</tr>
<tr>
<td>Femur and Knee Joint</td>
<td>4,423</td>
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<tr>
<td>Pelvis and Hip Joint</td>
<td>1,696</td>
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Rheumatology Group Practice in 2007

<table>
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</thead>
<tbody>
<tr>
<td>Total Visits</td>
<td>42,669</td>
</tr>
</tbody>
</table>
Orthopaedic Volumes

The total number of surgeries, including upper and lower extremity surgeries, has steadily grown.
**Functional Outcomes**

Functional outcomes were measured within the framework of three different registries: the mail-based Hip and Knee Registry started in 2001, the office/mail-based Shoulder Registry started in 2000 and the office-based OrthoMiDaS Registry started in 2006. The first two registries target midterm outcomes (one year and longer). The OrthoMiDaS Registry collects patient-reported outcomes when patients come to the office to see doctors; as such, it explores the functional status of various groups of patients, primarily during the early postoperative period (less than one year).

All registries are compatible. They capture sociodemographic characteristics, self-reported comorbidities and validated health-related general quality-of-life (HRQoL) SF36/12 (Short Form 36 and/or modified Short Form 12) instruments. The Shoulder Registry applies the validated Shoulder-Specific Questionnaire. All patients who visited the doctor’s office after March 2006 filled out a self-reported Musculoskeletal Review of Systems (MRoS) Questionnaire prior to seeing the doctor.

The 10 scores of the SF36/12 instruments reflect eight domains of general HRQoL and two composite scores. The eight domains are:

- Physical Functioning (PF)
- Role–Physical (RP)
- Bodily Pain (BP)
- General Health (GH)
- Vitality (VT)
- Social Functioning (SF)
- Role–Emotional (RE)
- Mental Health (MH)

The two composite scores are:

- Physical Health Composite Score (PCS)
- Mental Health Composite Score (MCS)

Both the SF36 and SF12 questionnaires were scored using normalized algorithms. The obtained scores have a mean value of 50 in the nonpatient population, and every 10 units correspond to one standard deviation from the norm. Values greater than 50 indicate better-than-average self-reported health, and values lower than 50 indicate worse-than-average self-reported health. Reference values of 50 are shown as horizontal yellow lines on all figures.

The Shoulder Questionnaire contains three domains:

- Function
- Pain
- Satisfaction

These domains produce one composite score:

- Total
The Function scale contains 20 questions; its score ranges from 0 to 60. The Pain domain is measured with three questions; its score ranges from 0 to 30. The Satisfaction domain is represented by one question; its score ranges from 0 to 10. The sum of these three scores represents the Total shoulder-specific quality-of-life score, which ranges from 0 to 100. Higher scores correspond to better shoulder-specific quality of life.

Baseline information for the Shoulder Registry was collected in the office prior to patients seeing the doctor during their preoperative visit. Yearly postoperative follow-up information was collected either during the office visit or, for patients who did not come back for follow-up visits, via mail. The registry contains data on 1,057 patients operated on between 2000 and 2006 (1,159 surgeries) who met the inclusion criteria, completed baseline questionnaires and were eligible for follow-up data collection. A total of 1,083 surgeries were followed with at least one postsurgical questionnaire application (follow-up rate: 93 percent).

The Musculoskeletal Review of Systems Questionnaire contains eight visual analog scale (VAS) domains and produces six derivative scores.

The eight VAS domains pertain to:
- physical problems associated with the neck (Neck)
- physical problems associated with the left arm (Index Arm or Other Arm)
- physical problems associated with the right arm (Index Arm or Other Arm)
- physical problems associated with the left leg (Index Leg or Other Leg)
- physical problems associated with the right leg (Index Leg or Other Leg)
- physical problems associated with the spine (Spine)
- physical problems associated with other medical conditions (Other)
- emotional problems associated with musculoskeletal conditions (Emotion)

The six derivative scores pertain to:
- Index Arm
- Other Arm
- Index Leg
- Other Leg
- Arms (average of the Left Arm and Right Arm)
- Legs (average of the Left Leg and Right Leg)

The scores range from 1 to 10. Higher scores correspond to better quality of life.
Total Shoulder Replacement for Primary Osteoarthritis

A total of 144 patients completed the SF36/12 questionnaires and the validated shoulder-specific questionnaire at baseline and follow-up. All patients had primary osteoarthritis, and all had undergone a total shoulder arthroplasty. Their average age was 68.0 years (range: 38–89), and 55 percent were male.

Patients took approximately one year to complete their rehabilitation and reach their maximum level of improvement from surgery. Some 93 percent of patients had a successful surgical outcome, based on reaching or exceeding a minimum 15-point improvement over their preoperative Total score (the average preoperative Total score was 29 points). Some 79 percent of patients realized at least a 30-point improvement. The average postoperative Total score was 82 points. On average, the functional results were sustained over at least five years of follow-up.

The SF36/12 scores were generally less sensitive to changes associated with shoulder problems. They demonstrated that these patients on average were healthy and did not have any serious mental dysfunction. On average, these patients had normal scores for General Health (GH), Vitality (VT), Mental Health (MH) and Role-Emotional (RE), and a normal Mental Health Composite Score (MCS). Shoulder replacement did result in significant and sustained improvements in the Role-Physical (RP) and Bodily Pain (BP) scores and in the Physical Health Composite Score (PCS), all of which were low prior to surgery.
Humeral Resurfacing Hemiarthroplasty with and without Soft-Tissue Glenoid Interposition

A total of 32 patients with primary or secondary degenerative arthritis underwent humeral resurfacing (nonstemmed implant) without glenoid resurfacing or the use of soft-tissue glenoid resurfacing (glenoplasty). Indications for surgery were younger age and a high activity level. Patients' average age was 43.5 years (range: 17–81), and 82 percent were male. Maximum follow-up was four years. The results were less favorable than those seen with standard total shoulder arthroplasty. The final functional recovery was slower, as some patients took more than a year to reach their maximum level of improvement. Some 85 percent of patients achieved a satisfactory outcome, and 67 percent had an improvement of more than 30 points in their Total scores; this compares with 93 percent and 79 percent, respectively, for patients who underwent standard total shoulder replacement. Also noted was an early trend toward deterioration in results over the first four years. This trend will require further study.

The difference between hemiarthroplasty with and without soft-tissue resurfacing of the glenoid will also require further study in a larger patient population. At no time after this type of surgery did the average patient satisfaction reach the level of patient satisfaction seen with standard total shoulder arthroplasty. The relative merit of hemiarthroplasty with or without soft-tissue interposition compared with standard total shoulder arthroplasty in the active patient younger than 50 years of age requires further study. The results presented for humeral resurfacing are very similar to our results with stemmed total shoulder replacement in older patients with osteoarthritis.

Shoulder-Specific Quality of Life (N = 27)

General Quality of Life (N = 32)

PF = Physical Functioning
RP = Role-Physical
BP = Bodily Pain
GH = General Health
VT = Vitality
SF = Social Functioning
RE = Role-Emotional
MH = Mental Health
PCS = Physical Component
MCS = Mental Component
Stemmed Hemiarthroplasty for Severe Osteoarthritis in Patients with an Intact Rotator Cuff

Older patients with severe glenohumeral arthritis are on occasion candidates for hemiarthroplasty. In some cases, the rotator cuff is thin; in other cases, the loss of glenoid bone is severe, which makes the placement of a glenoid component difficult. The results of hemiarthroplasty in this series of patients (average age: 65.5 yr; range: 38-85; 64 percent male) were less favorable than those seen with total shoulder arthroplasty.

Shoulder-Specific Quality of Life (N = 14)

General Quality of Life (N = 22)

PF = Physical Functioning
RP = Role-Physical
BP = Bodily Pain
GH = General Health
VT = Vitality
SF = Social Functioning
RE = Role-Emotional
MH = Mental Health
PCS = Physical Component
MCS = Mental Component
Shoulder Replacement for Rheumatoid Arthritis

A total of 27 patients with rheumatoid arthritis and minimum one year follow-up were treated with either hemiarthroplasty or total shoulder arthroplasty between 2002 and 2006. The patients’ average age was 63.9 years (range: 28-83), and 27 percent were male. The shoulder scores were improved, reaching a maximum level of improvement between one and two years from surgery. Some 90 percent of patients reached the minimum threshold for successful surgery (a 15-point improvement in shoulder score); 69 percent had an improvement of more than 30 points. The severity and systemic nature of rheumatoid arthritis was reflected in the deterioration of results over the first five years after surgery. This is most likely due to persistent and new onset of rotator cuff pathology after shoulder replacement. The SF36/12 data for Physical Functioning (PF), Role-Physical (RP), Bodily Pain (BP) and Physical Health Composite Score (PCS) reflected the same findings as those reflected in the shoulder score. This would suggest a deterioration in shoulder Function or overall deterioration in bodily Function associated with the systemic disease process.

Shoulder-Specific Quality of Life (N = 22)

General Quality of Life (N = 27)

PF = Physical Functioning  RP = Role-Physical  BP = Bodily Pain
GH = General Health        VT = Vitality       SF = Social Functioning
RE = Role-Emotional        MH = Mental Health  PCS = Physical Component
MCS = Mental Component
Hemiarthroplasty for Rotator Cuff Tear Arthropathy

Rotator cuff tear arthroplasty results in severe shoulder disability, which was reflected in the very low preoperative Total shoulder scores; scores for Physical Functioning (PF), Role-Physical (RP) and Bodily Pain (BP); and the Physical Health Composite Score (PCS) seen on the SF36/12. The patients in this series were older (average age: 69.9 years; range: 50–84), and 29 percent were male. They had lower-than-average General Health (GH), Vitality (VT) and Social Functioning (SF) scores as seen on the SF36/12. Of 31 patients with rotator cuff tear arthropathy who were operated on between 2001 and 2006, 82 percent had a satisfactory outcome as reflected by an improvement of at least 15 points in postoperative scores. However, only 50 percent had a better-than-30-point improvement over preoperative shoulder scores; the average postoperative score was 60 points. These results appeared to be sustained over the first five years after surgery.

Shoulder-Specific Quality of Life (N = 27)

General Quality of Life (N = 31)

PF = Physical Functioning  
RP = Role-Physical  
BP = Bodily Pain  
GH = General Health  
VT = Vitality  
SF = Social Functioning  
RE = Role-Emotional  
MH = Mental Health  
PCS = Physical Component  
MCS = Mental Component
Reverse Total Shoulder Arthroplasty for Rotator Cuff Tear Arthropathy

Reverse total shoulder arthroplasty has been performed at Cleveland Clinic since November 2003. Our early results with this prosthetic procedure in 43 patients with primary rotator cuff tear arthropathy are presented. The average age of these patients was 70.9 years (range: 35-88), and 41 percent were male. The SF36/12 data again demonstrated that this group had more comorbidities and lower Vitality (VT) and Social Functioning (SF) scores than did patients with osteoarthritis who were undergoing primary anatomic total shoulder replacement. Patients who underwent a reverse total shoulder replacement for primary rotator cuff tear arthropathy achieved an average postoperative score of 70 points, which was 10 points higher than the average score for hemiarthroplasty. Some 85 percent of patients had a significant improvement in postoperative Total score (15–30 points better than their preoperative score), and 64 percent of patients experienced an improvement of more than 30 points over their preoperative score. The superiority of the reverse total shoulder procedure over hemiarthroplasty was due almost entirely to improvements in the Function component of the shoulder score.

Shoulder-Specific Quality of Life (N = 34)

General Quality of Life (N = 43)

PF = Physical Functioning
RP = Role-Physical
BP = Bodily Pain
GH = General Health
VT = Vitality
SF = Social Functioning
RE = Role-Emotional
MH = Mental Health
PCS = Physical Component
MCS = Mental Component
Reverse Total Shoulder Arthroplasty for Failed Hemiarthroplasty To Treat Proximal Humeral Fractures

A reverse total shoulder replacement for a failed hemiarthroplasty after failed surgery for a proximal humeral fracture presents a challenge that cannot be managed by anatomic prosthetics. Of the 21 patients in this series (average age: 66.1 years; range: 45–84; 42 percent male), five had infection requiring a two-stage revision. Remarkably, 89 percent of these patients were significantly (at least 15 points) improved after surgery; 47 percent had an improvement of more than 30 points. The results of the first three years’ experience with this procedure are encouraging.

Shoulder-Specific Quality of Life (N = 19)

General Quality of Life (N = 21)

PF = Physical Functioning
RP = Role-Physical
BP = Bodily Pain
GH = General Health
VT = Vitality
SF = Social Functioning
RE = Role-Emotional
MH = Mental Health
PCS = Physical Component
MCS = Mental Component
Arthroscopic Rotator Cuff Repair for Full-Thickness Rotator Cuff Tears

A total of 113 full-thickness rotator cuff tears (1-3 tendons) were repaired by arthroscopic means. The average age of the patients in this series was 58.9 years (range: 32-83), and 64 percent were male. Almost all of these patients had minimal or moderate tendon retraction (midhumeral head) and grade 2 or less muscle atrophy. The SF36/12 data showed that these patients had normal scores for General Health (GH), Vitality (VT), Social Functioning (SF) and Mental Health (MH), as well as a normal Mental Health Composite Score (MCS) prior to surgery. The results of arthroscopic repair were satisfactory or better in 88 percent of patients, with 74 percent achieving a greater-than-30-point improvement in their Total shoulder score. The average postoperative score was 87 points (preoperative average: 41).

Shoulder-Specific Quality of Life (N = 113)

General Quality of Life (N = 110)

PF = Physical Functioning
RP = Role-Physical
BP = Bodily Pain
GH = General Health
VT = Vitality
SF = Social Functioning
RE = Role-Emotional
MH = Mental Health
PCS = Physical Component
MCS = Mental Component
Open Rotator Cuff Repair for Full-Thickness Rotator Cuff Tears

A total of 63 patients with large, chronic tears (grade 3 and 4 atrophy) and more than moderate retraction were indicated for open rotator cuff surgery. Their average age was 58.8 years (range: 16–82), and 80 percent were male. In cases where a tear was not reparable at the time of surgery or when preoperative magnetic resonance imaging (MRI) suggested an irreparable tear, a muscle transfer was considered for selected patients (younger, active patients with significant weakness). For older, less active patients with primarily pain-related problems whose preoperative MRI demonstrated an irreparable tear, a limited-goals arthroscopic surgery was considered. The average preoperative Total shoulder score was 41 points, and the average postoperative score was 80. Overall, 88 percent of patients were improved, and 64 percent achieved an increase of more than 30 points over their preoperative score. Their general good health preoperatively and the improvements in Function and Pain scores postoperatively were reflected in their SF36/12 scores.

Shoulder-Specific Quality of Life (N = 63)

![Graph showing scores across time periods for various categories of shoulder-specific quality of life.]

General Quality of Life (N = 53)

![Graph showing scores across time periods for various categories of general quality of life.]

PF = Physical Functioning
RP = Role-Physical
BP = Bodily Pain
GH = General Health
VT = Vitality
SF = Social Functioning
RE = Role-Emotional
MH = Mental Health
PCS = Physical Component
MCS = Mental Component
**Muscle Transfer for Irreparable Rotator Cuff Tears**

Selected patients with irreparable rotator cuff tears that involved the supraspinatus and infraspinatus rotator cuff were treated with transfer of the latissimus dorsi muscle — and in some cases with a transfer of the teres major. The average age of these patients was 57.0 years (range: 32–74), and 71 percent were male. The average Total score increased from 40 to 70 points postoperatively. It took patients more than one year to reach maximum levels of improvement. The difference between these muscle transfer patients and patients who underwent rotator cuff repair was reflected in the Function and Satisfaction scores. Although 75 percent of these patients achieved significant improvement with muscle transfer (a minimum increase of 15 points in the postoperative score), only 35 percent demonstrated an improvement of more than 30 points. These results clearly reflect the salvage and reconstructive nature of this procedure.

**Shoulder-Specific Quality of Life (N = 20)**

![Graph showing changes in scores over time for Function, Pain, Satisfaction, and Total]

**General Quality of Life (N = 29)**

![Graph showing changes in scores over time for Physical Functioning (PF), Role-Physical (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role-Emotional (RE), Mental Health (MH), Physical Component (PCS), and Mental Component (MCS)]

PF = Physical Functioning  
RP = Role-Physical  
BP = Bodily Pain  
GH = General Health  
VT = Vitality  
SF = Social Functioning  
RE = Role-Emotional  
MH = Mental Health  
PCS = Physical Component  
MCS = Mental Component
**Total Hip Arthroplasty**

In this series of patients who underwent total hip arthroplasty, the average age was 60.1 years (range: 20–90); 52 percent of patients were male. Preoperatively, patients demonstrated very low scores for the Index Leg (1.8 on the 10-unit scale) and some functional deficiency in the Other Leg and the Spine. During the first two months after surgery, a significant positive effect was observed in terms of scores for the Index Leg, Other Leg, Spine and Emotion. This effect continued to increase over time in the Index Leg (average improvement: 4.2 units) and was partially sustained in the Other Leg. General quality-of-life ratings also demonstrated small but significant improvements in Physical Functioning (PF), Role-Physical (RP) and Bodily Pain (BP) scores and in the Physical Health Composite Score (PCS). By the end of the second year, these scores had almost reached the level of scores observed in nonpatient populations (score 50).

### Musculoskeletal Review of Systems (N = 252)

![Bar chart showing scores for different body parts over time](chart1)

### General Quality of Life (N = 1249)

![Bar chart showing scores for different dimensions over time](chart2)

PF = Physical Functioning  
RP = Role-Physical  
BP = Bodily Pain  
GH = General Health  
VT = Vitality  
SF = Social Functioning  
RE = Role-Emotional  
MH = Mental Health  
PCS = Physical Component  
MCS = Mental Component
Revision of Total Hip Arthroplasty, Both Components

The patients in this series, who had failed total hip arthroplasty, were treated with revision of the acetabular and femoral components. Their average age was 60.6 years (range: 32–84), and 49 percent were male. Improvement in the Index Leg during the first year after surgery was significant but modest (from 1.9 to 4.3 units on the 10-unit scale). It was accompanied by significant improvement in Emotion. All measured general quality-of-life domain scores were preoperatively lower than those in a control population. Scores for some of these domains — Physical Functioning (PF), Role-Physical (RP), Bodily Pain (BP) and Social Functioning (SF), as well as the Physical Health Composite Score (PCS) — steadily improved during the two years after surgery, but they remained lower than the control scores.

Musculoskeletal Review of Systems (N = 39)

General Quality of Life (N = 171)
Revision of Total Hip Arthroplasty, One Component

The average age of patients who had failed total hip arthroplasty and were treated with revision of the acetabular or femoral components was 61.9 years (range: 22-82); 50 percent of them were male. Improvement in the functional score of the Index Leg during the first year after surgery was modest (from 2.2 to 5.4 units on the 10-unit scale), but it was still greater than it had been after revision of both components. This improvement was accompanied by a significant improvement in the Emotion domain. Preoperatively, all measured general quality-of-life domains were lower than those of the control group. Some of them — Physical Functioning (PF), Role–Physical (RP) and Bodily Pain (BP), as well as the Physical Health Composite Score (PCS) — steadily improved during the two years after surgery, but they remained lower than the control scores.
**Hip Arthroscopy with Debridement**

Hip arthroscopy with debridement is a procedure of choice for acetabular labrum tears. The mean age of the patients in this series was 40.8 years (range: 18–68); 43 percent were male. Baseline score of the Index Leg was low (2.7 units on the 10-unit VAS). During the first two months after surgery, it had improved significantly (by 2.1 units). Functional improvement was followed by a small but significant improvement in the Emotion parameter. A lack of data does not allow us to draw any conclusions about the functional dynamics of the Index Leg after the first two months of observation. During the early recovery period, no improvement in general quality of life was observed. But by the end of the first year, improvements in several domains of general quality of life — as reflected by increases in scores for Physical Functioning (PF), Role-Physical (RP) and Bodily Pain (BP), as well as the Physical Health Composite Score (PCS) — were small but significant.

**Musculoskeletal Review of Systems (N = 32)**

![Graph showing score changes over time for different body parts](image)

**General Quality of Life (N = 58)**

![Graph showing score changes over time for different domains](image)

PF = Physical Functioning  
RP = Role-Physical  
BP = Bodily Pain  
GH = General Health  
VT = Vitality  
SF = Social Functioning  
RE = Role-Emotional  
MH = Mental Health  
PCS = Physical Component  
MCS = Mental Component
**Total Knee Arthroplasty, Unilateral**

In this series of patients who underwent total knee arthroplasty, the average age was 63.9 years (range: 18-97); 35 percent of patients were male. The initially low Index Leg scores (2.1 units on the 10-unit scale) improved significantly during the early postoperative period and had reached a level of 6.0 by the end of the first year. Many of these patients had bilateral knee problems, as indicated by the low Other Leg score (6.3 units). Improvement in the preoperatively low scales of general quality of life was significant; the most prominent changes were observed during the first year.

![Graph showing Musculoskeletal Review of Systems](image)

**Musculoskeletal Review of Systems (N = 295)**

![Graph showing General Quality of Life](image)

**General Quality of Life (N = 1334)**

PF = Physical Functioning  
RP = Role-Physical  
BP = Bodily Pain  
GH = General Health  
VT = Vitality  
SF = Social Functioning  
RE = Role-Emotional  
MH = Mental Health  
PCS = Physical Component  
MCS = Mental Component
Total Knee Arthroplasty, Bilateral

The average age of patients who underwent total arthroplasty of both knees was 64.1 years (range: 48-82); 61 percent of these patients were male. In general, these patients were healthier than patients who had undergone unilateral knee arthroplasty; specifically, fewer of them had Neck, Arms and Spine problems. Preoperatively, the average score of both Legs (3.4 units on the 10-unit scale) was low, and this score did not improve significantly during the initial two months of postoperative evaluation. However, the Legs score did reach a level of 6.7 by the end of the first year. Improvement in the initially low domains of general quality of life was significant; the most prominent changes were observed during the first year, and improvement continued during the second postsurgical year.
**Revision of Total Knee Arthroplasty**

This series involved patients who had failed primary knee arthroplasty. Their average age was 61.8 years (range: 35-86), and 45 percent were male. Preoperatively, their Index Leg scores were extremely low (1.6 units on the 10-unit scale). Patients had some dysfunction in the Other Leg (6.8 units), and their Emotion score was relatively low (5.4 units). Postoperative improvements in Index Leg and Emotion scores during the first year were statistically significant, although they were much less prominent than the improvements seen after their primary knee arthroplasty. General quality of life preoperatively was low in all measured domains; it improved significantly after the surgery, although it did not achieve the level of the nonpatient population during the first two postoperative years.
Anterior Cruciate Ligament Reconstruction

Anterior cruciate ligament (ACL) insufficiency results in functional instability, and the knee can give way during cutting and pivoting activities. Instability can be corrected with ACL reconstruction. ACL reconstruction is performed with the patient’s own autograft hamstrings or patellar tendon or with an allograft tendon obtained from a tissue bank. In this series of ACL reconstructions, patients were younger than those in the other studied groups (average age: 31.7 years; range: 18-62); 60 percent were male. Except for the Index Leg, these patients were mostly healthy, as reflected by their scores related to Neck, Arms, Other Leg and Spine (all scores were close to 10). Preoperatively, patients demonstrated lower-than-normal scores for their Index Leg on the musculoskeletal review of systems and on the Physical Health Composite Score (PCS) of the SF36/12. During the first two months after surgery, these scores further decreased due to the postoperative limitations of function. However, they began to improve quickly after two months of recovery. Most patients were not expected to return to full activity until after six months.
Knee Arthroscopy with Meniscectomy

Meniscus tears in the knee result in focal pain in the joint. The focal pain is accompanied by mechanical symptoms such as catching, locking and pain with twisting or pivoting. Knee arthroscopy with partial meniscectomy to remove the unstable injured meniscal tissue can alleviate these symptoms. Preoperatively, the patients in this series (average age: 54.3 years; range: 19-81; 40 percent male) had low Index Leg scores on the musculoskeletal review of systems. They demonstrated modest improvement in the Index Leg score during the first two months after surgery and no further improvement thereafter. Improvements in initially low domains of general quality of life were significant but small.

Musculoskeletal Review of Systems (N = 119)

![Bar chart showing scores for Neck, Arms, Index Leg, Other Leg, Spine, Other, and Emotion over time: Pre-op, 0-2 mo, 2-12 mo.]

General Quality of Life (N = 243)

![Bar chart showing scores for PF, RP, BP, GH, VT, SF, RE, MH, PCS, and MCS over time: Pre-op, 0-2 mo, 2-12 mo, 12-24 mo.]

PF = Physical Functioning
RP = Role-Physical
BP = Bodily Pain
GH = General Health
VT = Vitality
SF = Social Functioning
RE = Role-Emotional
MH = Mental Health
PCS = Physical Component
MCS = Mental Component
Diabetic Foot Ulcers

Foot ulcer is one of the most common pathologies treated in the Diabetic Foot Clinic. A patient often comes to his or her initial visit with one or more ulcers that have been present for many months or even years. The Diabetic Foot Care Program has been tracking ulcer healing rates for patients who presented to Cleveland Clinic with ulcers in 2007. In the literature, a meta-analysis examining outcomes of neuropathic ulcers on the plantar aspect of the foot determined that 24.2 percent of ulcers were healed by three months (12 weeks), and 30.9 percent were healed by five months (20 weeks). In our Diabetic Foot Care Program, 52.7 percent of ulcers had healed by three months, and 68.1 percent had healed by five months (statistical analysis was performed with the time-to-event Cox model for competing risks). Standard treatment at Cleveland Clinic includes offloading (total contact cast, cast walker, half-shoe) and comprehensive wound care management, which incorporates newer wound treatment modalities. For some patients, ulcer healing is not possible without surgical intervention, which includes partial amputation or reconstructive surgery to correct any severe deformities that contribute to ulcer formation. In the presence of infection, a complete amputation may be necessary. With aggressive treatment and infection prevention, we have shown that better outcomes for diabetic foot ulcers are possible.

Patient Characteristics (N = 58)

- 2% No loss of protective sensation, but presence of peripheral arterial disease
- 21% Loss of protective sensation and presence of peripheral arterial disease
- 74% Loss of protective sensation, but no presence of peripheral arterial disease
- 3% No loss of protective sensation and no presence of peripheral arterial disease

Time-to-Event Analysis of Diabetic Foot Ulcers Treatment
Spine Problems (Neurological Institute)

In 2007, we performed a total of 2,112 surgeries on 1,854 patients.

**Diagnostic Mix**

- 98 Non-spine
- 118 Infection
- 123 Tumor
- 187 Fracture/Trauma
- 198 Deformity
- 1,317 Degenerative
- 71 Other

**Procedural Mix**

- 23 Hardware Removal
- 26 Hardware Insertion
- 26 Deformity
- 67 Tumor
- 86 Non-spine
- 173 Vertebral Augmentation
- 559 Arthrodesis
- 988 Decompressive
- 13 Biopsy
- 151 Other

Spine Problems (Neurological Institute) In 2007, we performed a total of 2,112 surgeries on 1,854 patients.
Rheumatology

Antiproteinase 3 Antineutrophil Cytoplasmic Antibodies and Disease Activity in Wegener Granulomatosis


The utility of antineutrophil cytoplasmic antibody (ANCA) levels to guide the management of patients with Wegener granulomatosis remains controversial. The goal of this study was to determine whether decreases in proteinase 3 (PR3)–ANCA levels are associated with shorter time to remission and whether increases are followed by relapse. This issue was felt to be of great clinical significance because clinicians in practice often use change in titers of these antibodies as a reliable guide to treatment decision-making.

In collaboration with investigators in the Wegener’s Granulomatosis Etanercept Trial (WGET) Research Group, change in titers of PR3–ANCA and disease activity and probability of relapse were analyzed. The study was prospective and included eight United States medical centers that were participating in a treatment trial for Wegener granulomatosis.

One hundred fifty-six patients with Wegener granulomatosis enrolled during periods of active disease. The PR3–ANCA levels were only weakly associated with disease activity. Changes in PR3–ANCA levels explained less than 10 percent of the variation in disease activity. Increases in PR3–ANCA levels were not associated with relapse. Decreases in PR3–ANCA levels were not associated with shorter time to remission.

These findings suggest that PR3–ANCA levels cannot be used to guide immunosuppressive therapy. We expect these results to modify physician behaviors in the use of ANCA as a prognostic tool.

Change in Disease Activity and PR3–ANCA in 156 Patients with Wegener Granulomatosis

54 relapsed ← 116 sustained remission (>6 mos) → 62 remission continued

↓

2 concurrent ANCA rise

9 ANCA rise within previous 12 mos

4 ANCA rise > 12 mos before relapse

31 no increase in ANCA

8 negative ANCA

Among 40 percent of all patients studied who had an increase in ANCA, relapse occurred within less than 1 year. Relapses often occur without a change in ANCA or with negative ANCA values. PR3–ANCA titer changes do not predict disease relapse in Wegener granulomatosis.

Conclusion: Relapses often occur without a change in ANCA or with negative ANCA values.
Bone Mineral Density Response to Teriparatide in Treatment-Naïve Patients and Patients Previously Treated with a Bisphosphonate

Elizabeth A. File, MD, and Chad Deal, MD

rh PTH 1-34 (teriparatide) (TPTD) is approved for the treatment of patients at high risk for fracture. Pretreatment with a bisphosphonate has been shown to blunt the bone mineral density (BMD) response to TPTD in some but not all studies. This study evaluated whether previous exposure to a bisphosphonate would blunt the skeletal response to TPTD.

A retrospective analysis of patients given a prescription for TPTD at Cleveland Clinic from January 2003 to July 2006 was performed. Patients were stratified into two TPTD treatment arms: bisphosphonate-naïve patients and those previously treated with a bisphosphonate. The primary outcomes were the absolute changes in lumbar spine, total hip and femoral neck BMD after ≥ 12 months of TPTD therapy. Secondary outcomes included the percentage change in markers of bone turnover (urinary N-telopeptide of type I collagen [NTX]), osteocalcin and alkaline phosphatase. We evaluated the percentage of patients who developed significant hypercalcemia, defined as a calcium level ≥ 11.0 mg/dL on one occasion or > 10.5 mg/dL on two or more occasions.

The cohort included 96 Cleveland Clinic patients, 66 of whom met the criteria for the primary outcome analysis. Inclusion criteria were the following: BMD measurement < 12 months prior to initiation of TPTD, a follow-up BMD measurement after ≥ 12 months of therapy with TPTD, and the availability of bone turnover markers drawn before and after initiation of TPTD therapy. Thirty patients were bisphosphonate-naïve, and 36 patients had received a bisphosphonate prior to initiation of TPTD.

There was no significant difference between the two groups in the mean absolute change in the lumbar spine, total hip or femoral neck BMD after ≥ 12 months of therapy with TPTD. Both treatment arms had significant increases in NTX and osteocalcin with no significant difference in the percentage change of response. In the entire cohort, significant hypercalcemia occurred in 20 of 96 patients (21 percent) receiving TPTD. Patients with hypercalcemia had a higher mean baseline calcium level (10.0 vs. 9.6 mg/dL). Only 1 patient (< 1 percent) discontinued TPTD due to hypercalcemia.

In our cohort, previous exposure to a bisphosphonate did not blunt the anabolic effect of TPTD. There was no significant difference in the percentage change in bone turnover markers in the two groups. Calcium elevations were frequent in patients on TPTD, but discontinuation of therapy was rare.

Absolute Change in BMD after ≥ 12 Months of Therapy with Teriparatide

Wilcoxon Two-Sample Test

* Bisphosphonate
Dual-Energy X-ray Absorptiometry Performance in Women Older than 65 Years

Osteoporosis is a major public health issue. Current quality measures by HEDIS (Healthcare Effectiveness Data and Information Set) require measurement of bone density and/or therapy in women with fracture. In order to reduce the burden of osteoporosis-related morbidity and mortality, organizations including the NOF (National Osteoporosis Foundation), ISCD (International Society for Clinical Densitometry) and the U.S. Preventive Services Task Force have recommended bone density measurement for women older than 65 years.

Since 2000, Cleveland Clinic’s Center for Osteoporosis and Metabolic Bone Disease and our Regional Medical Practice Osteoporosis Program have developed programs to increase the use of bone density measurements in women older than 65 years. Educational programs for primary care physicians and non-physician clinicians were begun in 2000. In 2003, a best-practice alert was instituted that resulted in a pop-up reminder in the electronic medical record at the patient visit if dual-energy X-ray absorptiometry (DEXA) had not been performed. The alert allows the healthcare provider to order a DEXA scan or record whether the patient has had a DEXA scan outside Cleveland Clinic. Patients who were offered DEXA but refused were excluded from the analysis.

In 2000, only 33 percent of women older than 65 years had DEXA performed. Compliance continues to improve. The percentage of women who had DEXA has risen from 33 percent to 88 percent.

Increases in the Percentage of Women Aged ≥ 65 Years Who Underwent Dual-Energy X-ray Absorptiometry Since 2000

<table>
<thead>
<tr>
<th>Year</th>
<th>Patients (Percent)</th>
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<tbody>
<tr>
<td>2000</td>
<td>33</td>
</tr>
<tr>
<td>2005</td>
<td>60</td>
</tr>
<tr>
<td>2006</td>
<td>80</td>
</tr>
<tr>
<td>2007</td>
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Persistent Hematuria in Patients with Wegener Granulomatosis: Renal Injury and Incomplete Repair or Active Disease Following Apparent Induction of Remission?

Marina Magrey, MD, Tiffany Marie Clark, CNP, Alexandra Villa-Forte, MD, MPH, and Gary S. Hoffman, MD, MS

Background: Wegener granulomatosis (WG) is a systemic disease that is often associated with an immune-mediated form of glomerulonephritis (GN). Renal disease most often manifests as microscopic hematuria with or without red blood cell (RBC) or mixed cellular casts, proteinuria, and an elevated serum creatinine concentration.

Objective: To determine whether persistent hematuria, in the setting of apparent clinical remission, may reflect glomerular injury and not active renal disease.

Methods: Analysis of data from 82 patients with new-onset WG, of whom 25 had GN at presentation.

Results: Twenty of 25 patients with GN achieved sustained remissions (> 6 consecutive months duration). During initial periods of active disease, the median peak serum creatinine was 1.9 mg/dL (range: 0.6–13.6). The median time to remission was 4 months (range: 2-13). After effective therapy, median creatinine was 1.1 mg/dL (range: 0.4–1.8). Ten of 20 patients had prolonged hematuria over a period of > 6 months. Within this subset, five subsequently normalized urine over a median period of 11 months and five did not achieve normal urine over a median follow-up period of 38 months. Thus, 10 of 25 patients with WG and GN had sustained hematuria in spite of apparent prolonged clinical remission.

Conclusion: Patients with WG and GN may achieve enduring remissions that allow for withdrawal of medications in spite of continued microscopic hematuria with or without RBC casts for months or even years. Continued use of aggressive immunosuppressive therapies in such patients would be ill-advised and could lead to irreversible and even life-threatening side effects from cyclophosphamide or high-dose corticosteroids.
Purified Protein Derivative Using the Mantoux Method

Biologic therapies have been used since 1998 for the treatment of patients with rheumatoid arthritis and other inflammatory arthritis (psoriatic arthritis and ankylosing spondylitis). A variety of agents — including tumor necrosis factor inhibitors, interleukin 1 inhibitors, T-cell modulators and B-cell-specific agents — have come into clinical use. Successful use of these agents requires careful monitoring of both efficacy and toxicity. Patients treated with these agents have an increased risk for infection. The increased risk for active tuberculosis is in most instances a result of reactivation of latent infection in patients treated with these agents. While no definitive guidelines exist for pretreatment evaluation for latent tuberculosis, most experts agree that a purified protein derivative (PPD) using the Mantoux method for skin testing should be performed. A negative PPD test should be verified prior to institution of these therapies.

Clinicians working in Cleveland Clinic’s Department of Rheumatic and Immunologic Diseases (Orthopaedic and Rheumatologic Institute) have established a new quality initiative that involves PPD skin testing. As of 2007, a PPD skin test is required for all eligible patients who are started on a biologic infusion. Clinicians are now required to document a negative PPD skin test prior to the initiation of biologic infusions or are required to indicate a valid reason why PPD skin testing was not performed. In 2007, biologic infusions were indicated for 46 patients. Ninety-eight percent (45/46) of those started on infliximab, abatacept, anakinra or rituxan at Cleveland Clinic had documentation of a negative PPD test in 2007 prior to initiation of the infusion (three of those patients had a documented negative PPD test from a physician in the surrounding community). In the case of the one remaining patient without documentation of a negative PPD skin test, the biologic infusion was initiated but stopped for other reasons.
Prognosis of American Patients with Takayasu Arteritis

Kathleen Maksimowicz-McKinnon, DO, Tiffany Marie Clark, CNP, and Gary S. Hoffman, MD, MS

Takayasu arteritis (TAK) is a granulomatous vasculitis of unknown etiology that affects the aorta, its major branches and the pulmonary arteries. The outcomes of patients with TAK — including clinical, laboratory and radiographic manifestations — were assessed. We evaluated the response to interventions, remission and relapse rates and disease progression of TAK in an American cohort and compared these observations to cohorts from the United States, Japan, India, Italy and Mexico.

Seventy-five patients followed at Cleveland Clinic’s Center for Vasculitis Care and Research were retrospectively studied using a uniform database that included clinical, laboratory and imaging data. Vascular imaging studies were performed at least yearly to monitor disease progression. The median age at onset was 26 years. Ninety-two percent of patients were Caucasian and 89 percent were female. Median duration of follow-up was 3.0 years.

Common manifestations at disease onset included loss or asymmetry of pulse (57 percent), limb blood pressure discrepancy (53 percent) and bruits (53 percent). Eleven percent of patients were asymptomatic prior to disease diagnosis. Initial angiographic studies demonstrated aortic abnormalities in 79 percent of patients and frequent involvement of the subclavian (65 percent) and carotid (43 percent) arteries.

Ninety-three percent of longitudinally followed patients attained disease remission of any duration, but only 28 percent sustained remission of at least 6 months’ duration after prednisone was tapered to less than 10 mg/dL. Both angioplasty and vascular surgery procedures were initially successful, but recurrent stenosis occurred in 78 percent of angioplasty and 36 percent of bypass/reconstruction procedures. More than two-thirds of patients were impaired in carrying out routine daily activities, and approximately one-quarter of all patients were occupationally disabled.

Disease manifestations in our cohort were similar to the NIH, Italian, Japanese and Mexican cohorts in female predominance and disease manifestations but differed from the Indian cohort in that the latter group had a higher frequency of males, abdominal aorta and renal artery involvement, and hypertension.

While symptomatic improvement usually follows glucocorticosteroid therapy, relapses usually occur in TAK with dose reduction. Attempts to restore vascular patency are often initially successful, but restenosis occurs frequently. Chronic morbidity and disability occur in most patients with TAK in the U.S. This concept is not widely appreciated in the U.S. and other Western countries.
Recurrence of Stenosis following Angioplasty and Vascular Surgery

Dr. Carol Langford was awarded a 2-year, $100,000 pilot project grant from the Rare Diseases Clinical Research Network (RDCRN), National Institutes of Health. This grant supports mechanistic and biomarker analyses in conjunction with the RDCRN-sponsored trial examining abatacept (CTLA4-Ig) in mild relapsing Wegener granulomatosis.

Disability and Mortality in Takayasu Arteritis

Dr. Carol Langford was awarded a 5-year, $3.8 million contract award to conduct concurrent pilot studies in giant cell arteritis and Takayasu arteritis to examine the safety, efficacy, and immunologic effects of abatacept in large-vessel vasculitis from the National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health.
**Efficacy of Infliximab, an Anti-Tumor Necrosis Factor-α Agent, in Giant Cell Arteritis (GCA).**


Giant cell arteritis is an inflammatory vasculopathy affecting large and medium-sized arteries. Glucocorticoids are highly effective in GCA treatment but smoldering disease activity may persist for years. Additional immunosuppressive treatments as steroid-sparing agents have been considered for treatment. This trial was designed to evaluate the efficacy of infliximab, an anti-tumor necrosis factor-α agent, in giant cell arteritis (GCA).

The trial design was a randomized, double-blind controlled trial at the Cleveland Clinic and 22 sites in the United States, the United Kingdom, Belgium, Italy, and Spain. Forty-four patients with newly diagnosed GCA that was in glucocorticosteroid-induced remission were randomly assigned to receive infliximab or placebo.

Primary end points were the number of patients who remained free of relapse through week 22. These end points were measured through week 22, when an interim analysis was done that resulted in early discontinuation of the planned 54-week trial. Infliximab therapy did not increase the proportion of patients without relapse at week 22 compared with placebo, nor did it increase the proportion of patients whose glucocorticosteroid dosages were tapered to 10 mg/dL without relapse.

This trial provides evidence that using infliximab as maintenance therapy in patients in glucocorticoid-induced remission of newly diagnosed giant cell arteritis is of no benefit and may be harmful. This study was the first randomized, placebo-controlled, double-blind, multicenter trial of standardized treatment with glucocorticosteroids and adjunctive treatment with placebo or infliximab in patients with newly diagnosed giant cell arteritis. The results should result in caution about the use of such therapy, which intuitively appeared to be quite rational, but in fact was of no benefit.

**Proportion of Relapse-Free Subjects through Week 22**

![Proportion of Patients (Percent)]

- Placebo: 40% (N=8/16)
- Infliximab 5 mg/kg: 40% (N=12/28)

Primary endpoint includes relapses, nl ESR, symptoms and increase pred
Anesthesiology

The Section of Anesthesia for Orthopedic Surgery continues its emphasis on the management of perioperative normothermia (≥36.0°C). Although the trend in 2007 was neutral, the addition of this measure in early 2008 to the Anesthesiologist Dashboard clinical practice reporting tool for staff anesthesiologists will provide data for continuous improvement.

### Perioperative Normothermia

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<td>4th Qtr</td>
<td>60</td>
<td>65</td>
<td>68</td>
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</tr>
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</table>

The Department of General Anesthesiology visits total joint replacement inpatients on their second postoperative day to evaluate the early postoperative period and to obtain patients' responses to a standardized anesthesia experience survey. One of the questions patients are asked is how much they agree or disagree with the following statement: “I threw up or felt like throwing up.” The chart below shows the percentages of patients who disagreed with that statement. Results for 2006-2007 are shown below.

### Management of Postoperative Nausea and Vomiting

<table>
<thead>
<tr>
<th>Year</th>
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<tr>
<td>N</td>
<td>377</td>
<td>107</td>
</tr>
<tr>
<td>%</td>
<td>84.1%</td>
<td>80.2%</td>
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Another question in the postoperative patient satisfaction survey asks for a response to the statement, “I was satisfied with my anesthesia care.” The chart below shows the percentages of patients who agreed with that statement. Results for 2006 and 2007 are shown below.
Surgical Quality Improvement

Surgical Care Improvement Program (SCIP)

SCIP is a national campaign aimed at reducing surgical complications by 25 percent by the year 2010. SCIP is sponsored by the Centers for Medicare and Medicaid Services (CMS) in collaboration with a number of other national partners serving on the steering committee, including the American Hospital Association (AHA), Centers for Disease Control and Prevention (CDC), Institute for Healthcare Improvement (IHI), The Joint Commission and others. Cleveland Clinic is committed to improving the care of surgical patients and participates in SCIP. A multidisciplinary team including the Surgery Institute, Anesthesiology Institute, Infectious Disease Department, Nursing Institute, and Quality and Patient Safety Institute works together to ensure that our surgical patients receive appropriate care.

Appropriate Preoperative Prophylactic Antibiotic Timing 2007

* Source: United States Department of Health and Human Services, Hospital Compare
Most current reported discharges July 2006 to June 2007.
“Top Hospitals” represent the top 10 percent of reporting hospitals nationwide.
National average of all reporting hospitals in the United States.

Appropriate Prophylactic Antibiotic Selection 2007

* Source: United States Department of Health and Human Services, Hospital Compare
Most current reported discharges July 2006 to June 2007.
“Top Hospitals” represent the top 10 percent of reporting hospitals nationwide.
National average of all reporting hospitals in the United States.
**Prophylactic Antibiotics Discontinued within 24 Hours After Surgery 2007**

![Graph showing the percentage of prophylactic antibiotics discontinued within 24 hours after surgery.]

* Source: United States Department of Health and Human Services, Hospital Compare
Most current reported discharges July 2006 to June 2007.
“Top Hospitals” represent the top 10 percent of reporting hospitals nationwide.
National average of all reporting hospitals in the United States.

**Recommended Venous Thromboembolism Prophylaxis Received by Patient 2007**

![Graph showing the percentage of recommended venous thromboembolism prophylaxis received by patients.]

* Source: United States Department of Health and Human Services, Hospital Compare
Most current reported discharges January 2007 to June 2007.
“Top Hospitals” represent the top 10 percent of reporting hospitals nationwide.
National average of all reporting hospitals in the United States.
Recommended Venous Thromboembolism Prophylaxis Ordered 2007

* Source: United States Department of Health and Human Services, Hospital Compare
Most current reported discharges January 2007 to June 2007.
“Top Hospitals” represent the top 10% of reporting hospitals nationwide.
National average of all reporting hospitals in the United States.
Surgery Patients Who Received their Beta Blocker Perioperatively

* No national benchmark data available at this time
Patient Experience

Outpatient - Orthopaedics and Rheumatology Institute

We ask our patients about their experiences and satisfaction with the services provided by our staff. Although our patients are already indicating we provide excellent care, we are committed to continuous improvement.

Overall Rating of Care 2007

Overall Rating of Provider Care 2007

Would Recommend Provider 2007
Inpatient - Cleveland Clinic

With the support of the Center for Medicare and Medicaid Services (CMS) and its partner organizations, the first national standard patient experience survey was implemented in late 2006. Adult medical, surgical, and obstetrics and gynecology patients treated at acute care hospitals across the country are included in the survey. Results collected for initial public reporting, published on www.hospitalcompare.gov in March 2008, are shown here.

Overall Rating of Care (0 worst - 10 best scale)
October 2006 - June 2007

Would Recommend Facility
October 2006 - June 2007
Cleveland Clinic Program Shortens Recovery After Total Hip Replacement

As the demand for hip replacement surgery expands, Cleveland Clinic’s Department of Orthopaedic Surgery within the Orthopaedic and Rheumatologic Institute is at the forefront of the development of new multimodal approaches to improving patient outcomes and overall satisfaction. For many patients, satisfaction means a quicker discharge home and an accelerated return to daily routine. With this in mind, our postoperative care has focused on reducing pain and increasing their function at the time of discharge. Our Rapid Recovery (RR) program, initiated in 2006, is a collaborative effort between orthopaedic surgery, anesthesia acute pain management, physical therapy and nursing services. The goals of this program are to minimize immediate postoperative pain and emphasize early and frequent mobilization as a means of achieving these goals.

In addition to patient satisfaction, several other factors are prompting our efforts. Traditionally, patients were kept in the hospital for an average of four days after joint replacement surgery, and were then transferred to an inpatient rehabilitation center for 10 to 14 days. The current health care climate encourages an early discharge directly home when appropriate. Demographic data tell us that overall, patients receiving total joint replacements are younger and more active — and less willing or able to spend an extended period in convalescence. Additionally, third-party payors are becoming more selective in approving patients for inpatient rehabilitation stays.

With Cleveland Clinic’s Rapid Recovery program, the goal is to reduce pain and improve patient function as measured by meeting certain milestones earlier. Secondarily, we found that most patients benefited from a safe discharge home by postoperative day two or three (Figure 1). There is no anticipated subsequent inpatient rehabilitation; instead, patients undergo their initial physical therapy at home. Inclusion criteria were the same for patients in both groups.

Once it has been determined that the patient is hemodynamically stable and possesses the necessary strength, he or she stands and is assisted in ambulation to tolerance. Beginning on postoperative day one, the patient is seen twice a day for therapeutic range-of-motion and ambulation. We found that most patients can be safely discharged home by postoperative day two or three. After the initial period of home physical therapy, they are transitioned to an outpatient facility to continue rehabilitation.

Results indicate that by undergoing a RR protocol following a hip replacement, patients ambulate further, experience less pain, spend less time in the hospital and are discharged home vs. to a rehab facility at an increased frequency as compared with those in the traditional protocol.

The dedicated staff of the RR program includes three surgeons, five physical therapists and two case managers who work closely to optimize the entire experience. Because patients are hospitalized for such a short time, effective communication is essential between members of the healthcare team, the patient and his or her family to prepare properly for discharge.

Figure 1. A timeline comparing traditional and rapid recovery postoperative physical therapy pathways
Number of days the average hip replacement patient spent in the hospital and step-down unit through our “Rapid Recovery Program”

<table>
<thead>
<tr>
<th></th>
<th>Rapid Recovery</th>
<th>Traditional Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Length of Stay Avg in days (SD)</strong></td>
<td>3.5 (1.3)</td>
<td>4.4 (2.0)</td>
</tr>
<tr>
<td><strong>DISCHARGE DISPOSITION:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home</td>
<td>72.4% N=21</td>
<td>53.8% N=35</td>
</tr>
<tr>
<td>Rehabilitation Facility</td>
<td>27.6% N=8</td>
<td>46.2% N=30</td>
</tr>
<tr>
<td><strong>DISTANCE AMBULATED (feet)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POD#0</td>
<td>27.6</td>
<td>NOT TESTED</td>
</tr>
<tr>
<td>POD#1</td>
<td>74.3</td>
<td>27.9</td>
</tr>
<tr>
<td>POD#2</td>
<td>81.1</td>
<td>44.7</td>
</tr>
<tr>
<td>POD#3</td>
<td>94.5</td>
<td>67.3</td>
</tr>
<tr>
<td><strong>PAIN</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POD#0</td>
<td>3.8</td>
<td>NOT TESTED</td>
</tr>
<tr>
<td>POD#1</td>
<td>4.5</td>
<td>4.6</td>
</tr>
<tr>
<td>POD#2</td>
<td>1.4</td>
<td>4.6</td>
</tr>
<tr>
<td>POD#3</td>
<td>2.4</td>
<td>3.9</td>
</tr>
</tbody>
</table>
Managing Perioperative Pain after Total Knee Replacement

Wael Barsoum, MD, Mark Froimson, MD, Loran-Mounir Soliman, MD, George Muschler, MD, Victor Krebs, MD, Alison Klika, Mike Dombrowski, PA-C, and Dept. of Physical Medicine and Rehabilitation

The main goals for any joint replacement procedure are to relieve pain and restore function, allowing patients to improve their overall quality of life and remain as independent as possible. Improved surgical techniques (such as minimally invasive total knee arthroplasty), procedures and pain management allow for earlier and more aggressive rehabilitation following surgery.

At Cleveland Clinic, revolutionary new pain management protocols have been instituted in total knee replacement patients. The protocols aim to decrease pain and improve function in the short term for patients. All patients who undergo a unilateral primary knee replacement are eligible for the “Pain-Free Knee” program. For patients undergoing knee replacement, pain control is improved by the use of a femoral nerve catheter that stays in place for the first 24 to 48 hours. To facilitate a quicker resolution of motor and sensory block, surgeons administer shorter-acting spinal anesthetics prior to surgery. At the conclusion of each surgery, the tissues surrounding the joint are injected with an analgesic cocktail to provide enhanced early pain relief. As soon as the spinal block has worn off (after about two hours), a physical therapist performs a thorough evaluation, which focuses on assessing the strength of the operative joint as well as the contralateral joint and the upper extremities.

We are pleased to report that our data using this new pain protocol has led to patients having significantly less pain on each day of their hospitalization and improved function scores up to four weeks after surgery. Given the historical belief that knee replacement is one of the most painful interventions we perform, these data are remarkably promising. In addition, this program has allowed patients to be discharged more commonly directly home, and significantly more quickly. Specifically looking at Dr. Barsoum’s patients, there has been a 1.4-day decrease in length of stay for patients with the “Pain-Free Knee Program” compared with the traditional protocol.

FNC = Femoral Nerve Catheter
Clinical Trials in Tissue Engineering of Connective Tissues

Prosthetic joint replacement has been extremely successful in the older patient with more diffuse disease and joint deformity. Local arthritic lesions and focal traumatic cartilage loss has been difficult to treat, particularly in the young and active patient. In these lesions, joint preservation is preferred over prosthetic replacement. Arthroscopic debridement and microfracture have had limited success because the local tissues have a limited capacity to regenerate a functional articular cartilage. Several tissue engineering strategies have recently been proposed using autologous articular chondrocytes in suspension placed under an autologous periosteal flap of soft tissue sewn over the debrided articular cartilage defect. There has also been limited success with this treatment paradigm. Difficulties with this treatment relate to traumatic injury to the surrounding intact articular cartilage secondary to sewing the soft tissue flap, leaking of the cell suspension from the created compartment, overgrowth of the periosteal flap and incomplete incorporation of the cartilage regenerate with the surrounding intact articular cartilage.

The Department of Orthopaedic Surgery at the Cleveland Clinic (Drs. Iannotti, Parker and Miniaci) conducted the first and only phase I FDA clinical trial using a purified xenograft type I collagen matrix with embedded autologous articular chondrocytes cultured over a 10-to-14 day period to develop a tissue engineered articular cartilage substitute. This cultured gel-like material was implanted, at a second-stage surgery, into the debrided articular cartilage defect through a minimally invasive arthrotomy. One set of punches creates a precise and regular defect in the area of the damaged cartilage and a slightly larger graft material is press fit and adhered to the bone bed of the defect using a fibrin glue. This study was conducted on 10 patients and has been followed for > than 1 year, with 3-month interval outcomes evaluations, a 1-year post-implant arthroscopic second look and biopsy, and MRI at 1 month and 1 year postoperatively. Through collaboration with the Section of Musculoskeletal Radiology (Dr. Carl Winalski), Lerner Research Institute (Dr. Cahir McDevitt) and the Department of Pathology (Dr. Thomas Bauer), a thorough assessment of the cartilage implant was carried out at the 1-year evaluation and arthroscopic biopsy.

The average International Knee Documentation Committee (IKDC) validated outcomes score was 34 preoperatively, 21 at one month postoperatively, 46 at three months postoperatively, 52 at 6 months postoperatively, 61 at 9 months and 64 at 1 year. (Figure 1)

Excellent correlation between the IKDC score improvement, MRI follow-up, arthroscopic and histologic appearance is exemplified by one patient. His 1-year postoperative IKDC score was 94 with a profile of 61 preoperatively, 24 at 3 months, 67 at 6 months, and 82 at 9 months. His 1-year follow-up MRI revealed excellent fill and loss of subchondral edema (Figure 2), arthroscopy revealed excellent appearance of the articular cartilage (Figure 3) and the histology revealed “hyaline-like tissue” (Figure 4).
Dr. Elaine Husni was awarded a 2-year, $180,000 Clinical Investigator Fellowship Award from the American College of Rheumatology Research and Education Fund. This award supports investigation of atherosclerosis in rheumatoid arthritis.

Impact of Electronic Alerts on Preventative Cardiology Services for Patients with Systemic Rheumatic Disease: Implications for Patient Care

M. Elaine Husni, MD, MPH, Gary Hoffman, MD, Julie Huang, MD, and Stan Hazen, MD, PhD

Despite the known significant cardiovascular risk in patients with rheumatic disease, there is low utilization of preventive cardiology services. An automatic clinician alert system was implemented via the electronic medical record in June 2006. Any patient with a diagnosis of a systemic rheumatic disease seen in the Cleveland Clinic Department of Rheumatic and Immunologic Diseases triggered a “pop-up” alert recommending referral to Preventive Cardiology for cardiovascular risk assessment. The Section of Preventive Cardiology PreCIS® database was then queried using SAS data retrieval for a monthly report of patients referred from Rheumatology or for a diagnosis of autoimmune disease. Prior to this best practice clinical alert system, additional before/after interventions were also examined to see which modalities had the highest impact for increasing referrals to Preventative Cardiology for this high-risk group. These interventions included direct clinician-to-clinician interactions, academic grand rounds conferences, research seminars and staff meeting announcements devoted to the cardiovascular risk in systemic rheumatic diseases.

The highest impact was seen with the use of best practice clinical alert. Prior to implementation of the “pop-up” alerts, a total of 16 patients over 15 months were evaluated. The monthly average referral rate increased from 1.07 patients to 12.5 patients per month. The majority of these patients required some cardiac risk intervention, including initiation of statin therapy for dyslipidemia, electrocardiogram and/or non-invasive cardiac testing for suspicion of coronary artery disease.

Use of a best practice clinician alert system is a highly effective means of increasing referral of patients with systemic rheumatic diseases to preventive cardiology. Further research will be needed to determine whether adoption of similar best practice clinical alerts will result in reduced cardiovascular burden in this high-risk group.
Antiplatelet and Anticoagulant Therapy in Patients with Giant Cell Arteritis
Michael S. Lee, Scott D. Smith, Anat Galor, and Gary S. Hoffman

A study completed by the combined team of ophthalmologists and rheumatologists in the Center for Vasculitis Care and Research demonstrated that patients receiving low-dose aspirin or coumadin for cardiovascular risk had fewer ischemic events (visual loss and stroke) at presentation and in the course of therapy for giant cell arteritis (GCA).

Vision loss and cerebrovascular accidents are frequent in GCA. Antiplatelet and anticoagulant therapies reduce the risk of stroke in other populations. We sought to determine whether antiplatelet or anticoagulant therapy reduces ischemic complications in patients with GCA. A total of 143 cases were included with mean follow-up of 5 years. The cohort included 109 women (76%) and 34 men (24%); mean age was 71.8 years. A total of 104 (73%) patients had a biopsy-proven diagnosis. Eighty-six (60.1%) patients had received chronic antiplatelet or anticoagulant therapy, including 18 (12.6%) who did not start therapy until after an ischemic event had occurred. Antiplatelet agents or anticoagulants were not used in 57 (39.9%) patients. Overall, 11 of 68 (16.2%) patients suffered an ischemic event while receiving antiplatelet or anticoagulant therapy vs. 36 of 75 (48.0%) not receiving such therapy (p < 0.0005). Univariate analysis failed to show a statistical difference between groups in regard to cerebrovascular risk factors, age, gender or biopsy-proven diagnosis. Bleeding complications occurred in two patients taking aspirin, one patient taking warfarin, and five patients who did not receive anticoagulant or antiplatelet therapy.

Conclusions: Antiplatelet or anticoagulant therapy may reduce the risk of ischemic events in patients with GCA. An increased risk of bleeding complications was not observed.

Based on this analysis, we recommend low-dose aspirin therapy to all patients with GCA who have no contraindication to its use.

Characteristics of patients with or without ischemic events secondary to Giant Cell Arteritis*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Ischemic event</th>
<th>No ischemic event</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>71.1</td>
<td>73.3</td>
<td>0.15</td>
</tr>
<tr>
<td>Female, %</td>
<td>67.4</td>
<td>80.4</td>
<td>0.10</td>
</tr>
<tr>
<td>ESR, mm/hour</td>
<td>66.3</td>
<td>85.5</td>
<td>0.03</td>
</tr>
<tr>
<td>Platelet count, X10^-3/mm³</td>
<td>392</td>
<td>383</td>
<td>NS</td>
</tr>
<tr>
<td>Biopsy-proven diagnosis, %</td>
<td>76.1</td>
<td>71.1</td>
<td>NS</td>
</tr>
<tr>
<td>Cerebrovascular risk factors, %</td>
<td>67.4</td>
<td>69.1</td>
<td>NS</td>
</tr>
<tr>
<td>Aspirin at time of event, %</td>
<td>17.4</td>
<td>48.5</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Warfarin at time of event, %</td>
<td>4.4</td>
<td>13.2</td>
<td>0.04†</td>
</tr>
<tr>
<td>Clopidogrel at time of event, %</td>
<td>2</td>
<td>1</td>
<td>NS</td>
</tr>
</tbody>
</table>

* Except where indicated otherwise, values are the mean. An ischemic event represents vision loss or hemispheric stroke secondary to GCA.
†By multivariate logistic regression analysis.
Renal Graft Survival and Patient Mortality in Wegener’s Granulomatosis: A Case/Controlled Study
Curry L Koening, Carol A. Langford, H. Lester Kirchner, Andrew O’Connor, Emilio Poggio, Gary S. Hoffman

Renal transplantation in patients with Wegener’s granulomatosis is as safe and effective as in other patients with end-stage renal disease (ESRD). These conclusions are based on a recently completed study by members of the Center for Vasculitis Care and Research. This study has been presented at the international annual meeting of the American College of Rheumatology by one of our research fellows in vasculitis.

Background: Kidney transplantation is an important medical advance for patients with ESRD due to Wegener’s granulomatosis (WG). This study used data from the United States Renal Data System (USRDS) to compare renal graft survival and patient mortality rates in patients who underwent transplant for WG to patients who underwent transplant for other causes of ESRD.

Results: A total of 712 WG patients were matched to 1,424 controls. One hundred fifty-eight (22%) grafts failed in patients who underwent transplant for WG compared with 366 (26%) failed grafts in controls who underwent transplant (P = 0.04). Recurrent disease as a cause of graft failure occurred in 4.4% of both groups. The 5-year allograft survival rate for patients with WG and controls was 86.9% (95% CI 84.2-89.2) and 82.7% (95% CI 80.6-84.6), respectively. A total of 137 (19%) patients with WG died compared with 361 (25%) controls (p = 0.002). Infection was the most common cause of death in patients with WG (N=29, 21%). The 5-year patient survival rate for WG was 89.9% (95% CI 87.4-91.9) compared with 85.7% (95% CI 83.7-87.4) in controls.

Conclusions: Transplant recipients with WG had a lower rate of graft failure and mortality than patients who underwent transplants for other causes. Recurrent disease was an uncommon cause of graft loss.

Frequencies (%) of cause for graft loss

<table>
<thead>
<tr>
<th>Cause of Graft Loss</th>
<th>WG</th>
<th>Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrent disease</td>
<td>4.4</td>
<td>4.4</td>
</tr>
<tr>
<td>Chronic rejection</td>
<td>36.1</td>
<td>33.9</td>
</tr>
</tbody>
</table>

Patients with WG are suitable candidates for transplant.
Substitution of methotrexate for cyclophosphamide in Wegener’s granulomatosis: a 12-year single-practice experience

Limiting use of cyclophosphamide (Cytoxan) for Wegener’s granulomatosis can eliminate the risk of cystitis and bladder cancer. Prolonged or repeated courses of daily cyclophosphamide increase the risk of bone marrow suppression, infections, cystitis, bladder cancer and other malignancies, myelodysplasia and gonadal failure.

We conducted a retrospective review to assess outcomes of therapy in patients with newly diagnosed Wegener granulomatosis (WG) using methotrexate (MTX) for mild to moderate disease and short-term treatment with cyclophosphamide (CYC) followed by MTX for severe disease. Patients with WG were included if their initial plan of therapy and subsequent care were directly supervised by the Cleveland Clinic Center for Vasculitis Care and Research. Severe disease (immediately life-threatening or involving critical organs) was initially treated with CYC and glucocorticoids. Mild to moderate disease was initially treated with MTX and glucocorticoids if serum creatinine was less than 2 mg/dL. Following initial improvement of severe disease, treatment was changed to MTX if serum creatinine was originally less than 2 mg/dL or had diminished to less than 2 mg/dL. Disease activity was determined at each visit and later converted to a Birmingham Vasculitis Activity Score, as modified for Wegener granulomatosis (BVAS/WG). Laboratory monitoring of disease and treatment toxicity was initially weekly and never less than monthly. Eighty-two (32%) of 253 patients with WG referred to the Center for Vasculitis Care and Research met eligibility criteria. Ineligible patients did not have new-onset disease or were not able to be followed principally in our center.

Seventy percent of patients (57/82) initially had severe disease and received a short course of CYC for remission induction. In more than half of these patients, illness was judged to be severe because of pulmonary hemorrhage or rapidly progressive glomerulonephritis, including need for dialysis or neurologic abnormalities. All patients had improvement: remission was achieved in 50% (41/82) of patients within 6 months and in 72% (59/82) within 12 months. Sustained remission (BVAS/WG = 0 for at least 6 consecutive months) was ultimately achieved in 78% (64/82) of patients. Among the 75 (91%) patients who achieved remission of any duration, 45% had relapse within 1 year and 66% had relapse within 2 years following remission. Eighty-two percent of patients with relapse achieved subsequent remissions after additional treatment. About three-quarters of relapses were mild and promptly responded to treatment. Only 17% of patients developed serious infections. CYC-associated cystitis or bladder cancer did not occur in any patients. However, about three-quarters of all patients suffered some form of permanent morbidity. Mortality was only 3.7% and none of the 3 deaths were due to WG.

This experience supports our prior recommendations to avoid long-term therapy with CYC and use MTX for mild to moderate disease from the start of therapy, or after severe disease has improved after initial therapy with CYC. The high relapse rate following discontinuation of medication and high frequency of permanent morbidity also emphasizes the need for even better therapies.

Outcomes for new-onset WG.

1 Four (1.3%) patients excluded - following CYC, these patients were treated with azathioprine.

2 Sustained remission: BVAS/WG = 0 for at least 6 months.

*Death not related to active WG.
Time to remission did not differ between groups in whom treatment was initiated with CYC vs. MTX.

**Permanent Morbidity**

<table>
<thead>
<tr>
<th>Condition</th>
<th>No. (N = 82)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic lung disease</td>
<td>10</td>
<td>12.2</td>
</tr>
<tr>
<td>Chronic sinus disease</td>
<td>36</td>
<td>43.9</td>
</tr>
<tr>
<td>Saddle nose</td>
<td>10</td>
<td>12.2</td>
</tr>
<tr>
<td>Dialysis</td>
<td>6</td>
<td>7.3</td>
</tr>
<tr>
<td>Renal transplant</td>
<td>4</td>
<td>4.9</td>
</tr>
<tr>
<td>Visual loss</td>
<td>3</td>
<td>3.7</td>
</tr>
<tr>
<td>Subglottic stenosis requiring tracheotomy</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Subglottic stenosis not requiring tracheotomy</td>
<td>4</td>
<td>4.9</td>
</tr>
<tr>
<td>Hearing loss</td>
<td>23</td>
<td>28.1</td>
</tr>
<tr>
<td>Gangrene</td>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Bladder cancer</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other cancer</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>At least 1 of these chronic morbidities present</td>
<td>61</td>
<td>74.4</td>
</tr>
</tbody>
</table>
“Wrist-Fit” Anatomically Specific Fixation for Unstable Distal Radius Fractures

Dr. William Seitz has worked on the design and testing of a new minimally invasive fracture fixation system for the distal radius, which is specific to the anatomy of the distal radius. The system was designed using the Hahmann-Todd skeletal collection from the Museum of Natural History of Cleveland. Exact cast models of a selection of the two dozen distal radii from the smallest to the largest were taken and the surfaces digitally scanned to develop a low-profile plating system designed to contour to the anatomy of the palmar radial and dorsal surfaces of the distal radius. These implants are flexible enough to create a combined buttress plate and tension band effect, creating an extremely strong construct without the need for locking screw technology. Biomechanical studies have been carried out, which demonstrate stability, rigidity and ability to maintain reduction comparable to a variety of fixed angled locking plates. In addition, the anatomy-specific nature of the plates allows precise, secure dorsal and volar corner fragment fixation not possible with a uniplanar volar locking plate, which helps to secure and stabilize an otherwise unstable distal radio-ulnar joint.

A total of 51 patients have been treated with this FDA approved new “Anatomy-Specific” implant system. Of the 51 patients, 37 patients had acute fractures of the distal radius that were comminuted, unstable and intraarticular. The results were evaluated using the NYOH Wrist-Rating Scale, which equally weighs objective and subjective findings. A “fair” result would be the equivalent of a well-performed wrist arthrodesis (fusion). At the 1-year follow-up, using the NYOH, 24 patients were rated “excellent,” and 13 were rated “good.” There were no “fair” or “poor” results.

Fourteen patients were treated using the same implants for a variety of reconstructive procedures (partial radio-carpal arthrodesis, osteotomy for realignment of malunited fractures, management of non-united fractures). These are a more complex subset of patients with “limited goals.” None of these patients demonstrated any complications relative to the implants, and all implants functioned well for stable fixation.
Journal Articles


Eagleton MJ, Schaffer JL. The vascular surgery operating room: Development of an up-to-date operating room that will meet the demands of the vascular surgery patient and team. Endovascular Today. 2007 Aug;6(8):25-30.


Selected Research Initiatives

Hashkes, Philip
A Pilot, Multi-center, Randomized, Double Blind, Placebo Controlled, Ascending Dose, Safety, Tolerability and Preliminary Efficacy Study of Two Dose Levels of Rilonacept (IL-1 Trap) Administered Subcutaneously in Pediatric Subjects with Active Systemic Juvenile Idiopathic Arthritis (SJIA)

Mandell, Brian F.
Randomized, multicenter, double-blind, placebo-controlled efficacy and safety study of 8 mg PEG-uricase in two dose regimens in hyperuricemic subjects with symptomatic gout

Deal, Chad
Open Label Proof of Concept Study of IV Zoledronic Acid (ZA) 5 mg after Forteo in Postmenopausal Women

Husni, Elaine
PRECISION: Prospective Randomized Evaluation of Celcoxib Integrated Safety vs Ibuprofen Or Naproxen

Deal, Chad
Study CR9108963: A 12 month, randomized, double-blind, parallel-group, placebo and active-controlled dose-range finding study of the efficacy and safety of SB751689 in postmenopausal women with osteoporosis

Langford, Carol
Rare Diseases Clinical Research Network A Multi-Center, Open-label Pilot Study of Abatacept (CTLA4-Ig) in the Treatment of Mild Relapsing Wegener’s Granulomatosis (WG), Vasculitis Clinical Research Consortium (VCRC)

Langford, Carol
Rituximab Therapy for the Induction of Remission and Tolerance in ANCA-Associated Vasculitis (RAVE)

Deal, Chad
A Randomized, Double-Blind Study to Compare the Efficacy of Treatment with Denosumab versus Alendronate Sodium in Postmenopausal Women with Low Bone Mineral Density

WGET Research Group (Gary Hoffman, co-PI)
Wegener’s Granulomatosis Etanercept Trial (WGET) Longitudinal Study

Hashkes, Philip
Phase 2 Study of IL-1 Trap for Treatment of Familial Mediterranean Fever

Froimson, Mark
DVT Prevention in THA: CECT vs. LMWH

Barsoum, Wael
Efficacy of the bipolar sealer Aquamantys 6.0™ in Patients Undergoing Total Hip Arthroplasty
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Professor, Cleveland Clinic Lerner College of Medicine

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Lerner Research Institute/Immunology
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Lerner Research Institute/Biomedical Engineering
Guang Yue, PhD
Lerner Research Institute/Biomedical Engineering, Rehabilitation Institute,
Wellness Institute

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Abby G. Abelson, MD
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Rula Hajj-Ali, MD
Elaine Husni, MD, MPH
Anna P. Koo, MD
Brian F. Mandell, MD, PhD
Raymond J. Scheetz, MD
Alexandra Villa Forte, MD, MPH
William S. Wilke, MD

**Clinical Immunology**
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R.J. Fasenmyer Chair in Clinical Immunology

**Osteoporosis and Metabolic Bone Diseases**
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Abby Abelson, MD
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Bruce Long, MD
Angelo Licata, MD, PhD
Clinical Trials Director

**Pediatric Rheumatology**
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**Vasculitis Care and Research**
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**Regional Medical Practices**
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Chad L. Deal, MD (Solon)
Rajul Desai, MD, MPH (Solon)
Howard Epstein, MD (Beachwood)
Elizabeth File, MD (Strongsville)
Janice Granieri, MD, PhD (Westlake)
Bruce Long, MD (Luthern Hospital)
Judith Manzon, MD (Westlake)
Susan Mathai, MD (Westlake)
Alla Modell, MD (Independence)
Rochelle Rosian, MD (Solon)
Jeffrey Wisnieski, MD (Willoughby Hills)

**Anesthesiology**
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Chairman, General Anesthesiology
Robert Helfand, MD
Section Head
Loran Mounir-Soliman, MD
Associate Section Head
Harendra Arora, MD
Charanjit Bahniwal, MD
Matvey Bobylev, MD
Raymond Borkowski, MD
Demetrios Bourdakos, MD
Michael Ritchey MD
Brok Gretter, MD
Stacy Ritzman, MD
Mauricio Perilla M.D
Ehab Farag M.D
John Tetzlaff, MD

Some physicians may practice in multiple locations. For a detailed list including staff photos, please visit clevelandclinic.org/staff.
Contact Information

General Patient Referral
24/7 hospital transfers or physician consults
800.553.5056

Joint Reconstruction, Pediatrics, Tumor and Trauma Appointments/Referrals
216.444.2606 or 800.223.2273, ext. 42606

Hand and Upper Extremity Appointments/Referrals
Foot and Ankle/Podiatry Appointments/Referrals
216.444.6260 or 800.223.2273, ext. 46260

Sports Medicine Appointments/Referrals
216.444.2620 or 800.223.2273, ext. 42620

On the Web at clevelandclinic.org/ortho and clevelandclinic.org/arthritis

Institute Locations

Main Campus
9500 Euclid Ave./A41 Orthopaedics
Cleveland, OH 44195
216.444.2620

9500 Euclid Ave./A50 Rheumatology
Cleveland, OH 44195
216.444.5632

Orthopaedics and Rheumatology
Beachwood Family Health and Surgery Center
26900 Cedar Road
Beachwood, OH 44122
216.839.3000

Brunswick Family Health Center
3574 Center Road
Brunswick, OH 44212
330.225.8886

Independence Family Health Center
5001 Rockside Road
Crown Center II
Independence, OH 44131
216.986.4000

Solon Family Health Center
29800 Bainbridge Road
Solon, OH 44139
440.519.6800

Strongsville Family Health and Surgery Center
16761 SouthPark Center
Strongsville, OH 44136
440.878.2500

Westlake Family Health Center
30033 Clemens Road
Westlake, OH 44145
440.899.5555

Additional Contact Information

General Information
216.444.2200

Hospital Patient Information
216.444.2000

Patient Appointments
216.444.2273 or 800.223.2273

Special Assistance for Out-of-State Patients
Complimentary assistance for out-of-state patients and families
800.223.2273, ext. 55580, or email medicalconcierge@ccf.org

International Center
Complimentary assistance for international patients and families
800.884.9551 or 001.216.444.6404 or visit clevelandclinic.org/ic

Cleveland Clinic in Florida
866.293.7866

For address corrections or changes, please call 800.890.2467
Orthopaedic Surgery and Sports Health Only
Cleveland Clinic and Euclid Hospital Sports Health & Rehabilitation – Willoughby Hills
29017 Chardon Road
Willoughby Hills, OH 44092
440.516.5400

Orthopaedic Surgery - Euclid Hospital
Medical Office Building
99 Northline Circle, Suite 100
Euclid, OH 44119
216.692.7750

Sports Health & Rehabilitation at the Mandel Jewish Community Center
26001 South Woodland Road
Beachwood, OH 44122
216.378.6240

Rehabilitation Only
Cleveland Clinic and Euclid Hospital Sports Health & Rehabilitation – Mentor
7215 Center St.
Mentor, OH 44060
440.205.1714 or 440.942.3120
Cleveland Clinic Overview

Cleveland Clinic, founded in 1921, is a nonprofit multispecialty academic medical center that integrates clinical and hospital care with research and education. Today, 1,800 Cleveland Clinic physicians and scientists practice in 120 medical specialties and subspecialties, annually recording more than 3 million patient visits and more than 70,000 surgeries.

In 2007, Cleveland Clinic restructured its practice, bundling all clinical specialties into integrated practice units called institutes. An institute combines all the specialties surrounding a specific organ or disease system under a single roof. Each institute has a single leader and focuses the energies of multiple professionals onto the patient. From access and communication to point-of-care service, institutes will improve the patient experience at Cleveland Clinic.

Cleveland Clinic's main campus, with 37 buildings on 140 acres in Cleveland, Ohio, includes a 1,000-bed hospital, outpatient clinic, specialty institutes and supporting labs and facilities. Cleveland Clinic also operates 14 family health centers; eight community hospitals; two affiliate hospitals; a 150-bed hospital and clinic in Weston, Fla.; and health and wellness centers in Palm Beach, Fla., and Toronto, Canada. Cleveland Clinic Abu Dhabi (United Arab Emirates), a multispecialty care hospital and clinic, is scheduled to open in 2011.

At the Cleveland Clinic Lerner Research Institute, hundreds of principal investigators, project scientists, research associates and postdoctoral fellows are involved in laboratory-based research. Total annual research expenditures exceed $150 million from federal agencies, non-federal societies and associations, and endowment funds. In an effort to bring research from bench to bedside, Cleveland Clinic physicians are involved in more than 2,400 clinical studies at any given time.

In September 2004, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University opened and will graduate its first 32 students as physician-scientists in 2009.

Cleveland Clinic is consistently ranked among the top hospitals in America by *U.S. News & World Report*, and our heart and heart surgery program has been ranked No. 1 since 1995.

For more information about Cleveland Clinic, visit clevelandclinic.org.

Online Services

**eCleveland Clinic**

eCleveland Clinic uses state-of-the-art digital information systems to offer several services, including remote second medical opinions to patients around the world; personalized medical record access for patients; patient treatment progress for referring physicians (see below); and imaging interpretations by our subspecialty trained radiologists. For more information, please visit eclevelandclinic.org.

**DrConnect**

**Online Access to Your Patient’s Treatment Progress**

Whether you are referring from near or far, DrConnect can streamline communication from Cleveland Clinic physicians to your office. This online tool offers you secure access to your patient's treatment progress at Cleveland Clinic. With one-click convenience, you can track your patient's care using the secure DrConnect website. To establish a DrConnect account, visit eclevelandclinic.org or email drconnect@ccf.org.

**MyConsult**

**Remote Second Medical Opinion** is a secure online service providing specialist consultations and remote second opinions for more than 600 life-threatening and life-altering diagnoses. The MyConsult service is particularly valuable for people who wish to avoid the time and expense of travel. For more information, visit eclevelandclinic.org/myconsult, email eclevelandclinic@ccf.org or call 800.223.2273, ext 43223.