TOTAL HIP ARTHROPLASTY REVISION AMONG STATIN USERS

In recent years, studies have demonstrated that statins are associated with anti-inflammatory effects, antioxidant effects and improved endothelial function. In addition, a number of studies have reported that statins stimulate bone formation and improve fracture healing. This study assessed the impact of statin use on the risk of revision after primary total hip arthroplasty (THA).

Data were collected from the Danish Hip Arthroplasty Registry, a nationwide clinical database established in 1995. Additional data were obtained from the Danish Prescription Database, in order to identify individuals who were using statins at the time of surgery. For each patient identified with a THA revision, another without a revision was identified to serve as a control. Information was gathered concerning the covariates associated with the risk of revision, which included gender, age, surgical technique, comorbidities and a diagnosis indicating a need for primary THA. One hundred ninety-two patients and 473 controls filled at least one prescription for a statin between the primary THA and the revision. The rate of failure was compared between the statin users and the nonusers.

The 10-year failure rate of THA was less among the statin users than among the nonusers, with an adjusted relative risk of 0.34. The adjusted relative risk of revision in patients who filled one to four statin prescriptions, five to eight statin prescriptions, nine to twelve statin prescriptions and more than twelve statin prescriptions were 0.42, 0.34, 0.16 and 0.36 respectively. As the number of statin prescriptions increased, the relative risk of revision decreased, with the exception of patients who filled more than twelve statin prescriptions.

Conclusion: This study demonstrates that the use of statins is associated with a substantially lower revision risk following primary total hip arthroplasty.


SMOKING CESSATION AND ACUTE FRACTURE SURGERY

Since 1944, research has shown an association between smoking and increased postoperative complications. This study reviewed the effect of a smoking cessation intervention, instituted immediately after fracture surgery.

This study was a single-blind, randomized, controlled trial including patients who were daily smokers with an acute fracture of the lower or upper extremity. All injuries required an acute surgical procedure. Eligible patients were randomized to an intervention group, who received a standardized smoking cessation program for six weeks, or to a control group. All subjects were followed by nurses at three separate times during the 12 weeks post-surgery. The primary outcome was defined as the number of patients with at least one postoperative complication at six to 12 weeks.

A total of 298 eligible patients were asked to participate in the study. The portion of patients who had a postoperative complication was significantly higher in the control group than in the intervention group (p=0.048). Superficial wound infection was the most frequently recorded complication. A secondary analysis revealed the odds of a complication to be 2.51 times higher in the control group than in the intervention group.

Twenty-four of 48 patients in the intervention group and nine of 52 in the control group reported total abstinence from smoking at two weeks. The corresponding numbers at six weeks were 19 of 44 and 10 of 51.

Conclusion: This study found that a six-week smoking cessation program, started immediately after emergent fracture surgery, may significantly reduce the postoperative complication rate.


HYPERCHOLESTEROLEMIA AND ROTATOR CUFF DISEASE

Approximately 23% of individuals over 50 years of age have a rotator cuff tear. Although chronic degeneration appears to be responsible for the majority of spontaneous acute rotator cuff tears, several studies have suggested a relationship between lipid profiles and tendon ruptures. This study sought to determine whether patients with rotator cuff tears are more likely to have hypercholesterolemia than those without such tears.

This prospective study collected serum cholesterol and lipid profiles from a group of patients presenting to a clinic with shoulder pain. In an experimental group, a rotator cuff tear or rupture was diagnosed from history, physical examination maneuvers and MRI. The control group had a chief complaint of shoulder pain with no history of rotator cuff tear. Age, race, gender, height, weight, dominant extremity, affected arm, mechanism of injury, medical history, physical examination findings and MRI findings were all recorded for both groups. The
More patients with rotator cuff compared with those with rotator cuff tears, 235 had a full thickness tear and 140 had a partial tear. The patients were older and had unilateral shoulder pain for 10 years of age or older and had unilateral shoulder pain with no history of trauma. A diagnostic US was completed, determining that 375 patients had rotator cuff tears. From among these patients who were 18 years of age or older and had unilateral shoulder pain with no history of trauma, the researchers selected those with rotator cuff tears and those without tears. Of the patients with rotator cuff tears, 209 did not. Of those with rotator cuff tears, 235 had a full thickness tear and 140 had a partial tear. The patients were contacted to determine cigarette smoking history. The US results were contacted to determine cigarette smoking history.

**Conclusion:** This study found that patients with rotator cuff tears are more likely to have hypercholesterolemia than are those without such tears.


**CIGARETTE SMOKING AND ROTATOR CUFF TEARS**

Tobacco use is reported to be associated with musculoskeletal pain and dysfunction, but has not been implicated specifically as contributing to rotator cuff pathology. This study explored the relationship between cigarette smoking and the prevalence of rotator cuff tears.

This retrospective study included 2,356 consecutive patients referred for diagnostic ultrasound (US) to assess shoulder pain consistent with rotator cuff tear. From among these records, the researchers selected patients who were 18 years of age or older and had unilateral shoulder pain with no history of trauma. A diagnostic US was completed, determining that 375 patients had rotator cuff tears and 209 did not. Of those with rotator cuff tears, 235 had a full thickness tear and 140 had a partial tear. The patients were contacted to determine cigarette smoking history. The US results were compared with that history.

More patients with rotator cuff tears had a positive daily tobacco smoking history than did those without tears (p = 0.002). Patients with rotator cuff tears were more likely to have smoked regularly within the 10 years before presentation than were those without tears (p = 0.0006). In addition, the rotator cuff tear cohort had a higher mean pack per day smoking history than did the no rotator cuff tear group (p = 0.004). Finally, those with a rotator cuff tears had a longer duration of smoking (p = 0.05) and longer tobacco exposure than did those without tears (p = 0.0006).

**Conclusion:** This study revealed a strong association between tobacco abuse and rotator cuff disease. Thus, the authors suggest that smoking may be an important risk factor in the development of rotator cuff tears.


**CHOLECALCIFEROL AND EXTENDED PHYSICAL THERAPY AFTER HIP FRACTURE**

By the ninth decade of life, one in three women and one in six men will have sustained a hip fracture. As supplemental cholecalciferol has been shown to reduce falls and fractures in community dwelling and institutionalized older individuals, this study sought to determine whether the addition of physical therapy and cholecalciferol supplementation could reduce the rate of falls and hospital readmissions after a hip fracture.

One hundred seventy three patients, all 65 years of age or older and all with acute hip fracture, were studied. The subjects were randomly assigned to receive physical therapy for 30 minutes per day during acute hospitalization or to receive extended physical therapy, including acute hospital therapy plus a 30-minute per day home program. Half of the patients in each group were assigned 800 international units per day of cholecalciferol and the other 2,000 international unit per day. Falls and hospital readmissions were assessed by monthly telephone calls, patient diaries and a telephone hotline. Adherence to the intervention was assessed during those calls. A regression analysis was used to evaluate the effects of interventions on outcomes.
During the study, 45 withdrew from participation. During the 12 months of follow-up, 212 falls occurred; a rate of 1.43 per patient year. Extended physical therapy reduced the fall rate by 25%. There was no greater benefit of high dose cholecalciferol on the fall rate as compared to the low dose. There were 74 hospital readmissions, with a rate of 0.5 per year. A 39% reduction in hospital readmissions was noted in the high dose cholecalciferol group.

**Conclusion:** This study demonstrated that, post-hip fracture, extending physical therapy after hospital discharge reduced the rate of falls by 25%, while high dose vitamin D reduced the rate of hospital readmissions by almost 40%.


### AQUAPOРИN WATER CHANNELS AND SPINAL CORD INJURY

Spinal cord injury (SCI) is accompanied by a disruption of the blood-spinal cord barrier with subsequent extravasation of fluid and proteins. Edema at the injury site appears to develop in close association with necrosis at the lesion epicenter. Greater spinal cord edema is related to poorer neurologic outcome. Aquaporin 4 (AQP4) is a molecular water channel in the brain and spinal cord that is predominantly expressed in astrocytic processes in direct contact with blood vessels. It has recently been demonstrated that AQP4 is upregulated at the site of injury after a SCI. This study examined the role of AQP4 water channels after experimental SCI.

Both wild and AQP4 deficient, adult female mice were used in this study. Each animal underwent a T-10 vertebral contusion SCI. The subjects were then studied for locomotion, stepping patterns of the limbs at 42 days post-injury, bladder function, and, after sacrifice, by histochemical analysis. Test results were compared between the two groups.

The mice who were AQP4 deficient exhibited more impaired locomotor function and prolonged bladder dysfunction than did the wild type mice. Histologic examination revealed a greater loss of neurons and myelin in the AQP4 deficient mice. Spinal cord edema was persistently increased above control levels in the AQP4 deficient mice, but not in the wild type mice at 14 and 29 days post-injury.

**Conclusion:** This animal study demonstrates that aquaporin-4 deficient mice have impaired locomotor function, bladder dysfunction, greater tissue damage, and increased water content after contusion spinal cord injury. The authors suggest that AQP4 may play a protective role after SCI, by facilitating the clearance of tissue water.


### DIABETIC FOOT INFECTIONS AND HYPERBARIC OXYGEN THERAPY

Foot lesions among patients with diabetes are a major health problem with significant morbidity and mortality. Ulceration of the foot is the main predisposing factor leading to amputation in patients with diabetes mellitus. While hyperbaric oxygen therapy (HBOT) has been proposed as a safe treatment modality, only a few controlled, prospective studies have evaluated the efficacy of HBOT in wound healing. This study investigated the clinical results of HBOT in patients with diabetic foot ulcers.

This retrospective study involved 42 patients treated with hyperbaric oxygen for diabetic foot ulcers. Only those with grade three and four lesions were included in the analysis. Common infecting microorganisms involved were *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Enterococcus*. The treatment protocol combined medical and surgical treatments. All patients received HBOT in a diving chamber. Ten sessions of HBOT treatment were required as a treatment unit.

Each session was two hours in duration, with sessions occurring five days per week and intermittently on weekends. Treatment success was defined as the presence of a healed wound and preservation of the affected foot for at least six months after the completion of therapy.

**Conclusion:** This retrospective study found that adjunctive HBOT has a positive effect on wound healing in diabetic feet with infection.


### KINEMATIC IMPROVEMENT FOLLOWING BOTULINUM TOXIN-A INJECTION FOR UPPER LIMB SPASTICITY

After a stroke, upper limb spasticity can range from mild to severe. Treatment with oral medications often proves ineffective. This study tested the hypothesis that motor performance can be improved by botulinum injections in patients with upper limb spasticity due to stroke.

Eight patients were recruited, each with a single, clinical ischemic stroke event more than one year prior to the intervention. All were initially hemiplegic and, by testing time, had experienced marked motor recovery. Further, all demonstrated focal flexor spasticity compromising the elbow, wrist and fingers. The subjects were assessed for kinematics at baseline and were then administered botulinum toxin A. The injections were administered using anatomical landmarks and EMG-electrical stimulation guidance. In addition to the injections, the patients receive one hour each of standard physical therapy and occupational therapy twice per week.

Patients with stroke were slower than normal volunteers during both sessions. Although both groups...
demonstrated significant improvement between sessions, the improvement was greater in the spastic stroke group (p<0.05). Patients with spastic stroke required a longer time than did normal volunteers to grab an object during both sessions. However, after injection, the spastic stroke group improved their time (p≤0.005), while there was no modification in the control group between sessions (p=0.337). Additionally, a marked acceleration occurred in the peak velocity after injection in the treated group (p≤0.001), that was not seen in the control group (p=0.79).

Conclusion: This study demonstrates that, in a group of patients who had previously reached a plateau with standard therapy, improvement in kinematics could be achieved by botulinum toxin injection combined with additional physical and occupational therapy.


BOTOX VERSUS AMITRIPTYLINE FOR MIGRAINE

Amitriptyline (AM) is a commonly prescribed tricyclic antidepressant for the treatment of migraine. Despite the availability of various pharmacological alternatives, prophylactic agents against migraine have had inconsistent results. The trigeminal sensory fibers contain neurotransmitters including calcitonin gene related peptide (CGRP) and are considered important in the pathophysiology of migraines. As botulinum toxin type A (BTX-A) has been found to directly decrease the amount of CGRP released from trigeminal neurons, this study investigated the effects of BTX-A on chronic, daily migraines.

Patients between the ages of 18 and 60 years who suffered from chronic, daily migraines were randomized into two groups. The groups were treated with 25 or 50 mg per day of AM, or 250 units of BTX-A. Patients in the BTX-A group received injections divided into 15, pre-established points around the head.

All subjects were reevaluated at 30 day intervals for 90 days. The main endpoints included a reduction of at least 50% in the number of pain episodes, in the intensity of pain, and in the number of drug doses for pain, and reports of improvement by the patient or by the examiner.

Seventy-two subjects were included in the study. Reductions by at least 50% in the number of days of pain were recorded in 68% of the patients in the BTX-A group and 72% in the AM group (p=0.78). The reductions in pain intensity were 50% for the BTX-A group and 56% for the AM group (p=0.79). Eighty-eight percent of the subjects in the BTX-A group and 94% of those in the AM group fulfilled the criteria for improvement (p=0.65). Weight gain, somnolence, dry mouth and constipation were all more prevalent in the AM group (p = 0.0001, p = 0.0001, p=0.0045 and p = 0.0001, respectively).

Conclusion: This study suggests that BTX-A may be as effective as AM for the prophylactic treatment of chronic daily migraines. Further, side effects were more prevalent in the AM group.


TRANSCRANIAL STIMULATION FOR POST-STROKE APHASIA

Recent neuroimaging studies investigating aphasia recovery have found that improved speech production is dependent upon left frontal cortical activation. This study sought to determine whether direct manipulation of the left frontal cortex, through noninvasive transcranial stimulation, can improve naming accuracy among patients with stroke who suffer from aphasia.

Ten patients with chronic aphasia were recruited for this study. All had a history of left hemisphere stroke, an age of less than 85 years and right-hand dominance, and all were native English speakers. Those participants underwent two, randomized weeks of intervention. These treatments included one week of anodal transcranial direct current stimulation (A-tDCS) and one week of sham stimulation, both administered while performing a computerized, self-administered anomia treatment. Placement and polarity of the active electrode was determined by previous MRI and fMRI, used to localize the area of cortex with the highest level of activation during naming tasks. The primary outcome measure was the ability to name the test items, comparing scores at baseline, immediately after the fifth session of each treatment phase and one week after the final session. More items were named correctly after the active treatment than following the sham treatment (p<0.04). No other significant relationships were found. Additionally, improved naming performance was maintained at one week post-treatment.

Conclusion: This study found that anodal transcranial stimulation over the left frontal cortex can lead to enhanced naming accuracy in stroke patients with aphasia.


BRAIN COMPUTER INTERFACE

In an effort to provide paralyzed patients with some degree of functional restoration, researchers have been working on the development of brain-computer interfaces (BCIs). These systems aim to bypass the peripheral nerves and muscles by directly converting brain signals under conscious control into control signals for electronic devices. Recently, BCI systems using intracranial electrocorticographic (ECoG) electrodes have attracted interest. ECoG-based BCIs use signals acquired directly from the surface of the cortex. To date, studies have not addressed whether fMRI is sufficient to prelocalize the relevant regions for BCI purposes in individual subjects. The current study took a first step toward exploring this issue by combining fMRI activation patterns and the spatial distribution of responsive ECoG electrodes for electrode selection. The aim of this study was to assess the feasibility of targeting one, specific cognitive brain region (the left anterior dorsolateral prefrontal cortex, or DLPFC) for BCI control.

The subjects were three, consecutive patients with intractable...
epilepsy, scheduled for subchronic ECoG using subdurally placed electrodes to localize the seizure focus. Several weeks prior to grid implantation, the patients underwent a functional MRI scan during which they performed several tasks designed to localize functionally relevant regions. ECoG grid electrodes were surgically implanted. The patients then voluntarily modulated ECoG activity of the selected electrode to control the movement of a cursor on a computer screen. All subjects quickly gained accurate brain computer interface control by modulation of the dorsolateral prefrontal cortex signal. All three patients demonstrated good BCI control, with more than 80% correct hits documented.

**Conclusion:** This study demonstrates that the dorsolateral prefrontal cortex is suitable for use in brain computer interface applications.


**AUTOLOGOUS CHONDROCYTE IMPLANTATION**

Among the surgical interventions for full thickness cartilage tears of the knee, autologous chondrocyte implantation (ACI) is a recent development. This study investigated the long-term clinical results of ACI for full thickness cartilage lesions of the knee.

Included were patients with full thickness cartilage lesions of the knee who had been treated with ACI since 1987. Three hundred forty-one surveys were mailed to the treated patients, with 224 responding. All subjects completed five, subjective questionnaires. In addition, information concerning baseline measurements and features of cartilage lesions were collected retrospectively from the patients' medical files.

The follow-up period for the study averaged 12.8 years, while the average age at the time of surgery was 33.3 years. Seventy-four percent of the patients reported that they had been doing better or the same during the past year, while 26% reported that they were worse. Ninety-two percent were satisfied with the surgery and said that they would do it again. A subgroup analysis showed worse final outcomes for patients with bipolar lesions than for those with multiple unipolar lesions. In addition, the final outcome was not affected by age or lesion size.

**Conclusion:** This long-term follow-up of patients undergoing autologous chondrocyte implantation suggests that the clinical and functional outcomes of these patients remain high for up to 20 years after surgery.


**CEREBRAL MICROEMBOLIZATION DURING TOTAL HIP ARTHROPLASTY**

Much work has been published concerning cardiothoracic surgery, the incidence of cerebral microembolization and the consequent neuropsychological decline after coronary artery bypass graft surgery. Some studies have reported that the incidence of intraoperative cerebral microembolization during total joint arthroplasty is between 40% and 60%. However, these studies have not reported on cognitive changes associated with these emboli. This study investigated the occurrence and consequences of cerebral microembolization during total hip arthroplasty (THA).

This prospective study included patients scheduled for primary total hip arthroplasty between December of 2001 and December of 2003. Forty-five subjects were included. Neuropsychological assessments were completed preoperatively and again at six weeks and six months postoperatively. Intra-operatively, transcranial Doppler was used to measure the cerebral microemboli load. Continuous monitoring began before surgery and continued until no microemboli had been detected for a period of two minutes and when the patient was returned to the supine position after surgery. In addition to neuropsychological functioning, quality of life was assessed using the EuroQol, with orthopedic outcome evaluated using the WOMAC, the Harris Hip Score and the Oxford Hip Score.

No decline was seen in the mean neuropsychological performance after surgery. The incidence of microembolization was 23%. The prevalence of PFO was 37%. No significant relationship was seen between the presence of a patent foramen ovale and a higher incidence of total microemboli. Femoral component insertion generated the most emboli. Further, no significant relationship was found between total microemboli and age, operative time or discharge day.

**Conclusion:** This study demonstrated that intraoperative cerebral microembolization occurs in a substantial portion of patients during total hip arthroplasty. The microemboli load was low, however, and was not associated with a decrease in neuropsychological performance.


**DONEPEZIL FOR VASCULAR DEMENTIA**

Vascular dementia is the second most common type of dementia. No medications are currently approved for its treatment. Two prior donepezil studies in vascular dementia have demonstrated significant cognitive improvement, but inconsistent benefits in global functioning. This large study was undertaken to further evaluate the potential benefits of donepezil for patients with vascular dementia.

Participants included 974 patients with possible or probable vascular dementia. The patients were randomly assigned to an active treatment group, taking donepezil, 5 mg once a day, or to receive a placebo, for 24 weeks. The primary efficacy assessments included scores on the Vascular AD Assessment Scale Cognitive Subscale (V-ADAS-Cog) and the clinicians' interview-based impression of change plus a caretaker based interview, performed at baseline and at weeks six, 12, 18 and 24.

Patients treated with donepezil enjoyed significantly greater improvement than did those taking placebo on the V-ADAS-Cog at the endpoint and at all time points except week six. Patients with hippocampal...
DULOXETINE FOR CHRONIC BACK PAIN

Back pain is the leading cause of job-related disability in the United States. Duloxetine is a serotonin and norepinephrine reuptake inhibitor, with demonstrated efficacy for other pain conditions. This study investigated the efficacy and safety of duloxetine for the improvement of pain and function in patients with chronic low back pain (LBP).

This randomized, double-blind, placebo-controlled trial included 18 clinical sites in five countries. Patients older than 18 years of age with a six-month history of LBP were included in this study. All had a Brief Pain Inventory 24-hour pain score of at least four and were treated for 36 weeks. After a screening phase, a thirteen-week treatment phase was initiated. During that period, patients were randomized to receive either duloxetine 60 mg once daily or a placebo. For all nonresponders, the dosage of the duloxetine-treated patients was increased to 120 mg once daily. The primary outcome measure was pain reduction, based upon Brief Pain Inventory (BPI) 24-hour average pain scale scores.

Secondary efficacy measures included the patients’ global impressions of improvement (PGI-I) and change from baseline to endpoint in Roland-Morris Disability Questionnaire-24 (RMDQ-24) scores addressing chronic LBP and its interference with activities of daily living.

Patients treated with duloxetine enjoyed a significantly greater reduction in pain for 24 hours at all time points compared to placebo (p=0.016 at week four, p=0.001 at week seven and p=0.004 at week 13). In addition, the PGI-I score at endpoint also showed significantly greater improvement in patients treated with duloxetine than in those treated with placebo (p = 0.014). Patients treated with duloxetine also improved significantly in RMDQ-24 total scores at endpoint (p = 0.009).

Conclusion: This study of patients with chronic low back pain found treatment with a serotonin and norepinephrine reuptake inhibitor effective in reducing pain and disability.


FOREARM STRAP BRACE VERSUS WRIST SPLINT FOR LATERAL EPICONDYLITIS

The most common cause of lateral elbow pain is lateral epicondylitis. Two popular methods of treatment of this disorder include bracing with a forearm counterforce strap and use of a wrist extension splint. This study compared the outcomes of patients treated with these two devices.

This prospective, randomized study included 42 patients diagnosed with lateral epicondylitis. The participants were randomized to receive either a Velcro wrist extension splint or a forearm counterforce strap brace. Both groups were instructed to wear the devices during all daytime hours for a period of six weeks. Clinical outcome measures included the American Shoulder and Elbow Society Elbow Assessment (ASES) form, and the Mayo Elbow Performance (MEP) scale.

At six weeks, results on the ASES revealed improvement with both devices, with no significant difference seen between the two. However, worst pain scores declined more in the splint group than in the brace group (p=0.027). Both groups improved in MEP scores, with no significant difference noted between the two groups.

Conclusion: This study of patients with lateral epicondylitis found slightly better outcomes among patients who were treated with a wrist extension splint than those treated with a forearm strap brace.


EXERCISE WHILE PLAYING VIDEO GAMES

More than half of American adults play video games, with one in five playing every day or almost every day. This study sought to determine the energy expenditure (EE) and metabolic equivalent (MET) of activity with the Wii Sports and Wii Fit Plus software.

Twelve, healthy, Japanese men and women were recruited for this study. None had engaged in regular, intensive sports or physical activity for the past year. Each subject completed a metabolic chamber measurement under three different protocols, sitting rest, Wii Fit Plus balance and resistance exercises, Wii Fit Plus yoga and aerobic exercise and Wii Sports. Each activity was completed in a metabolic chamber, and was continued for at least eight minutes, in order to achieve a steady state of energy expenditure. The MET value was calculated from resting and steady-state EE during the activity.

The mean MET values of all 68 activities were distributed over a wide range, from 1.3 METs (lotus focus: balance exercise) to 5.6 METs (single arm stand: resistance exercise). The mean MET values of yoga, balance, resistance, and the aerobic exercise of Wii Fit Plus and Wii Sports were 2.1 and 3.0, respectively. The MET values of yoga and balance exercise were significantly lower than those of the resistance and aerobic exercise of Wii Fit Plus and Wii Sports. Forty-six of the activities were classified as light intensity and 22 as moderate intensity. No activity was considered heavy intensity, with a MET value of greater than six. The MET values of playing the Wii Sports versions of activities were markedly lower than those of the actual sports.

Conclusion: This study demonstrates that playing active video games can result in light to moderate intensity exercise, which...
Knee osteoarthritis (OA) is a common joint disorder. The initial treatment is often nonoperative and consists of patient education, weight reduction, physical therapy and, if needed, oral and injected medication. In selected patients with OA of the medial compartment, improvements in pain, function and loading forces have been reported with the use of valgus unloader knee braces. This study compared lateral wedged insoles with valgus bracing for patients with medial compartment knee OA.

This prospective, open-label, parallel, randomized, controlled study included patients with symptomatic medial compartment knee OA. The subjects were randomized to receive treatment with either a 10 mm laterally wedged insole or a valgus brace. All patients were assessed at six months using a visual analogue scale for pain, WOMAC scores, physical examinations and documentation of analgesic use and the mean number of hours per week that the participants had worn the device. The primary outcome measure was pain severity, with secondary outcomes including knee function, as assessed with the WOMAC scale.

At six months, there were no significant differences in pain reduction and WOMAC score improvements for laterally wedged insoles as compared with valgus knee bracing. According to published criteria for clinical trials in OA, 13% and 20% of the patients benefitted from either the insole or brace treatment, respectively. Neither treatment achieved correction of knee varus malalignment in the frontal plane. Treatment compliance in the insole group was greater than that in the brace therapy group. The lateral wedged insole was worn longer during the day for a mean of eight hours, as compared with 5.5 hours for the brace. Subgroup analysis revealed a better effect for the insole than for the brace for patients with mild, medial OA.

Conclusion: This study of patients with medial compartment knee osteoarthritis found that a laterally wedged insole can be as effective as valgus bracing for reducing pain and improving function.


GROWTH HORMONE, PERFORMANCE AND BODY COMPOSITION

The use of growth hormones (GHs) is prohibited by a number of governing bodies. This ban is based upon the assumption that these hormones can improve physical performance. However, the literature concerning the effects of these agents on performance is not clear. This study sought to determine the effects of GH alone or combined with testosterone on body composition and measures of performance.

This study included healthy recreational athletes, ages 18 to 40 years, who had engaged in regular training for the past 12 months. A total of 35 women and 68 men were involved in this eight-week treatment regimen with a six-week washout period. The participants were randomly assigned to receive either GH or a placebo. Men received GH plus testosterone, GH plus a placebo, testosterone plus placebo or double placebo. Women received either a placebo or GH. Body composition was measured before treatment and after eight weeks of treatment. Physical performance was measured before treatment, at eight weeks and after a six-week washout period.

The use of GH significantly reduced fat mass and increased extracellular water and body cell mass, with greater effects noted with GH and testosterone combined. GH did have a significant and positive effect on sprint speed (3.8%) at the end of eight weeks, with an increased effect noted with co-administration of testosterone in men (8.3%). However, these changes were not sustained after washout. GH did not significantly impact other physical performance characteristics, such as maximum oxygen consumption, dead lift or jump height.

Conclusion: This study suggests that growth hormone supplementation increases lean body mass, reduces body fat and increases sprint capacity. This effect was almost doubled when combined with testosterone in men. However, changes in performance were not sustained after discontinuation.


PRAMIPEXOLE FOR DEPRESSIVE SYMPTOMS OF PARKINSON'S DISEASE

Depression is common in patients with Parkinson's disease (PD) and is a major determinant of poor quality of life for these patients. Several studies have suggested that dopamine receptor agonists, such as pramipexole and pergolide, might be effective in reducing depression in patients with PD. This study investigated the effects of pramipexole on clinically relevant depressive symptoms in patients with PD.

Subjects were enrolled from 76 centers in 12 European countries and South Africa. Patients were included in the study if they were at least 30 years of age and were diagnosed with stable, mild to moderate PD under satisfactory control. All participants had clinically relevant depressive symptoms, as documented by the Geriatric Depression Scale.

The subjects were randomized to receive pramipexole at strengths ranging from 0.125 mg to 1 mg. Pramipexole was titrated for a maximum of five weeks, during which the dose was increased until an antidepressant effect was achieved. After titration, the patients received at least seven weeks of maintenance treatment. The study drug was then tapered off for a maximum of five days. Patients were seen for assessment and screening at baseline and at weeks one, two,
three, five, 12 (end of treatment) and 13. The primary efficacy endpoint was the change between baseline and 12 weeks in total scores on the Beck Depression Inventory (BDI).

The BDI scores decreased by an average of 5.9 points in the pramipexole group and by 4.0 points in the placebo group (p=0.01). Unified Parkinson’s Disease Rating Scale Motor scores decreased by 4.4 points in the pramipexole group and by 2.2 points in the placebo group (p=0.03). Adverse events were reported in 105 of the 144 in the pramipexole group and by 101 of 152 in the placebo group.

**Conclusion:** This study found that, among patients with mild to moderate Parkinson’s disease with symptoms of depression, the dopamine receptor agonist, pramipexole, reduced depression and improve depression-related quality-of-life.


*Regional Managing Editors

**Barone, P., et al.**