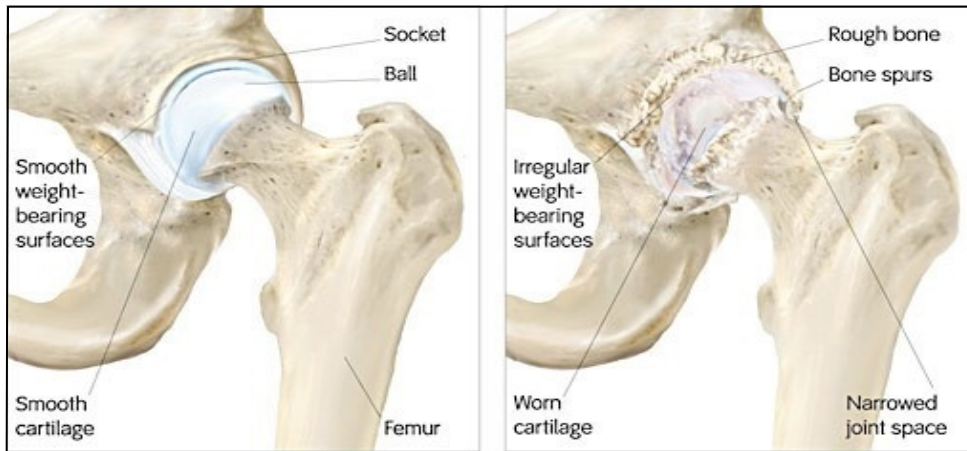


What is Hip Osteoarthritis?

Osteoarthritis (OA), also known as osteoarthrosis or degenerative joint disease (DJD), is a disorder of the joints caused by progressive loss of hyaline cartilage, sclerosis of subchondral bone, and the formation of bone spurs and cysts at the margins of the joint.^{1,6,9,11,17,22,42} OA of the hip joint occurs between and around the head of the femur and the acetabulum of the pelvis.



How big of a problem is it?

OA is the most frequent cause of musculoskeletal disability in developed countries and one of the most common causes of disability resulting in limited activities of daily living in the general adult population.^{9,22,27} In addition to the individual's personal pain and disability, OA has a huge financial impact on both the individual and the federal health care system as a whole. In the United States alone, it is estimated that the number of individuals with OA in any part of the body will increase from 43 to 60 million by 2020, resulting in an estimated cost of over 100 billion healthcare dollars per year.^{4,8,34,44}

Studies investigating prevalence of Hip OA, specifically, have cited between 10-25% in aging populations and 0.7 to 4.45% of the population overall.^{5,6,12, 23,25,31,39} A systematic review by Dagenais et al in 2009, yielded 23 studies reporting 39 estimates of overall prevalence ranging from 0.9% to 27% of populations with a mean of 8.0% and a standard

deviation of 7.0%.⁹

According to research presented at the 2006 American College of Rheumatology annual meeting, about 25% of Americans can expect to develop osteoarthritis of the hip during their lifetime.² Based on this research and the age and population of our country, there are between 18-24 million individuals suffering from some form of personal disability related to hip osteoarthritis.

The prevalence of Hip OA is rising dramatically and expected to continue to rise sharply in the next 20-30 years. Reasons for this dramatic increase stem from the aging of large groups of the population including the “baby boomers”, people living much longer with higher expectations and the increase of obesity rates among western populations.^{6,9,32} Iorio et al. found that obese individuals suffered twice the rate of hip and knee arthritis as compared to adults with healthy body weight. Nearly 32% of obese adults have arthritis, as opposed to 16% of those of normal weight and 22% of people who are overweight but not obese.²¹

What are the Signs and Symptoms?

The physical signs and symptoms of Hip OA are significant and occur as a result of the secondary changes to the joint. These secondary changes include, but are not limited to, capsular restriction, loss of mobility at the joint, weakness and tightness of surrounding musculature, increased pressure within the joint, general de-conditioning, loss of balance and proprioception, and overall increase in stress on surrounding joints including the knee, pelvis, and lumbar spine. As the OA progresses, many individuals will eventually have intolerable pain, lose their overall functional ability, independence, and quality of life.

The social and economic effects of Hip OA on the individual, and society as a whole, may be just as significant as the physical signs and symptoms. Overall, OA is the sixth leading contributor worldwide to total years lost to disability, or disability adjusted life years (DALYs).⁴ The direct and indirect societal costs attributable to OA are enormous. For example, individuals with OA are more likely to reduce work hours or stop working all together resulting in lost wages and income. Older adults with

symptomatic arthritis report greater medical utilization and health care costs compared with people not reporting arthritis.³⁸ Individuals with hip OA lose interest in participating in some of the most common leisure activities such as walking with friends, going to a dinner party, and engaging socially in fear of the pain involved. Rates of depression are higher in individuals with long-standing pain and loss of overall function.
28,29

The Old Treatment Approach

There is no cure for OA and it continues to progress throughout one's life. So what can be done about it? The good news is that there are treatments for the secondary changes that occur with OA. As stated earlier, it is these secondary changes that directly cause the pain, loss of function, and decreased quality of life.

The old model of medical treatment of OA included only pharmaceuticals/medications, exercise, weight management, and waiting for it to get painful enough to warrant surgical intervention. Medications are important and can be used to manage pain and inflammation, but they do not restore strength, flexibility, proprioception, and joint mobility; the root causes to the pain and functional disability in the individual. They also become very expensive and carry their own risks associated with long term use such as gastrointestinal bleeding, cardiovascular disease, and addiction.¹⁶

Many studies have shown that non-pharmacological treatment options, such as therapeutic exercise programs, can be very effective and emphasized.^{6,7,14,15,16,18,30,33,35,41,45,48} Therapeutic Exercise, when used alone, has been found to help biomechanically unload intra-articular pressure from within the hip joint leading to decreased pain response. This unloading occurs through improved flexibility, increased strength, improved mechanics and decreased overall weight of the individual.

However, utilization of commonly recommended self-management strategies such as exercise and weight loss have demonstrated questionable compliance among patients and clinicians alike.^{20,37,46} *If many studies have proven these effective, why would compliance by patients and referral by physicians be so poor?*

One important reason for this poor compliance is a progressive

Capsular Pattern of Restriction. The hip joint is surrounded by a deep connective tissue called the joint capsule. The joint capsule, in addition to ligaments, helps to stabilize and control the range of motion of the hip joint. As hip OA progresses, the joint capsule becomes inflamed and very tight causing the femoral head to migrate superiorly and severely restricting normal movement of the hip. This capsular tightening, inflammatory reaction and loss of range of motion increases pressure within the joint which causes immediate increased pain.

Many individuals show poor compliance with an exercise program because of the progression of the joint restriction and severe pain. The exercises cannot specifically target the progressive capsular restriction. The pain becomes so great that they are not able to tolerate exercise to lose weight, improve flexibility, and improve biomechanical strength as prescribed to them. The OA continues to progress, causing more pain and disability. The person remains inactive and suffering for years which leads to increased risk for many co-morbidities including depression, diabetes, addiction, obesity, heart disease, stroke and cancer. This continues until the hip becomes degenerative enough to warrant total hip replacement surgery.

Current Evidence-Based Medicine

Newer and more recent studies that have investigated the combination of manual therapy techniques, focusing on increasing capsular mobility of the hip, and therapeutic exercise have shown excellent results.^{6, 8, 17, 19, 26}

Manual therapy techniques are defined as those in which a medical provider, such as a physical therapist, osteopathic physician, or chiropractor, perform skilled hand movements intended to improve tissue extensibility, increase range of motion, induce relaxation, mobilize or manipulate soft tissues and joints, modulate pain, and reduce soft tissue swelling, inflammation, or restriction.³ There are a variety of manual therapy techniques that target the hip joint capsule with the goal of increasing its extensibility (See Figure 1 below).

The first and most widely used manual therapy technique to improve general hip joint capsular mobility and decrease pain immediately is termed Long Axis Hip Traction.^{6, 10, 17, 19, 40, 42, 48} The patient is lying supine while the

practitioner grasps the patient's leg near the ankle. The practitioner then places the leg in approximately 10-30 degrees of flexion, 10-30 degrees of abduction and slight external rotation for the most relaxed position of the hip joint. The practitioner then begins to pull at a certain force to distract the hip joint, stretch the joint capsule, and decrease intra-articular pressure. This technique immediately decreases pain and begins the process of increasing hip joint capsule extensibility, leading to decreased pressure within the joint, increased range of motion, and relaxation of surrounding muscles.

Alternating varying amounts of compression and decompression during the technique is also thought to be one of the mechanisms by which lubrication is enhanced within the joint. This technique is followed by many other specific and directional techniques performed by the

practitioner to target specific parts of the joint capsule and surrounding soft tissues of the hip joint. It is important to note that greatest benefit will come from combining all of these joint and soft tissue techniques, not just long axis traction alone. Long Axis traction is the first technique used because of its immediate pain relief and general capsular stretching. Oftentimes the patient will not tolerate more specific directional techniques initially.



(Figure 1: Physical Therapist performing Hip Long Axis Traction)

Combining manual therapy with specific therapeutic exercises shows the greatest promise for conservative treatment of hip osteoarthritis. By increasing the patient's mobility and decreasing their pain, they are better

able to perform their long-term exercise routine for decreased weight, increased flexibility, and increased biomechanical strength. These conservative measures can decrease the need for medications, improve patient morale, improve functionality, and most of all, improve quality of life.

Although this conservative treatment does not cure the arthritis nor prevent surgery at some point, the universal belief is that if you can lose weight, gain strength and mobility, and improve activity level, you have a greater chance of more comfortably delaying surgery until it is absolutely necessary. Every 3-6 months you can delay surgery is another 3-6 months of improved surgical techniques, surgical experience, improved surgical components and cost savings by the patient and the insurance company.

Individuals with hip OA, who seek conservative care such as physical therapy, usually receive manual therapy, exercise instruction, and education 1-2 x per week for 3-8 weeks depending on their specific level of dysfunction. Manual therapy is most effective by consistently accumulating the effects of one treatment on another. It is similar to how an antibiotic medication works on an infection. In order to effectively eliminate the infection, the person must consistently, and for the entire duration, take the antibiotic medication. Likewise, one session of mobilization on the hip joint is ineffective for mobility change or long term pain relief, but by accumulating the treatments consistently for a certain period of time, it has longer lasting effects.

These positive treatment outcomes combine Manual Therapy and Therapeutic Exercise in the clinic. After discharge from the clinic, performing only exercise at home, individuals are able to maintain improved range of motion, strength and pain levels up to 12-24 months.^{17,48}

Costs of No Treatment

Manual therapy and therapeutic exercise are covered expenses under health insurance plans and are far less expensive than the overall costs associated with NOT providing this care. In other words, by NOT treating non-surgical or pre-surgical cases of hip OA with manual therapy and therapeutic exercise:

1. Patient will be in more pain requiring more costly and risky medications.
2. Medication side-effects can lead to expensive treatments related to gastrointestinal disorders, cardiovascular problems, and/or addiction.
3. Patient will worsen in overall fitness and conditioning related to inactivity and potentially leading to more expensive treatments related to diabetes, obesity, heart disease, cancer, depression or stroke.
4. Psychosocial costs of not participating in life activities and socializing including lost wages from inability to work and treatment of depression.
5. Progression of physical weakening, capsular restrictions and inability to move normally results in other orthopedic dysfunctions and more importantly, advanced degenerative changes around hip and premature hip replacement surgery.

The costs of NOT providing conservative treatment, when appropriate, are well understood by the insurance companies and payers. They fully realize how much osteoarthritis is currently costing them. It is in the billions of dollars annually and this is why they support treatments that can reduce medication use, decrease rates of co-morbidities, and get people exercising.

What happens when conservativemeasures are exhausted?

There is no cure for osteoarthritis. As the disease progresses, many people, even with delayed surgery, greater quality of life and decreased co-morbidities, will still require surgical intervention. Joint replacement surgery has been shown to be very effective in improving pain and function. If there are no contraindications or limiting factors, it is the premier choice of treatment once conservative measures have been exhausted.

There are, however, some obstacles to having surgery. It is very expensive, carries its own risks associated with surgery under general anesthesia, and may have to be repeated depending on the age of the individual. Historically, it has been reserved for individuals older than 65, but there are more individuals seeking out surgery at a younger age.

Studies indicate that by 2030, 52% of patients needing primary hip replacements and 36% of those needing revision hip replacements will be younger than 65 years old.¹³

According to a study by Kurtz et al, by 2030, the demand for primary total hip replacements is estimated to grow by 174% to 572,000 and the demand for hip revision procedures is projected to double by the year 2026 with an increase of nearly 100,000.²⁴

Due to the lack of proper care and expectations of an active lifestyle, more and more individuals are seeking out joint replacement surgery earlier than they have in previous decades. These replacements will only function for approximately 15-20 years, which means more patients will require the more time-intensive and expensive revision surgery at a younger age.

There is another significant problem with the future of joint replacement surgery. The shortage of orthopedic surgeons that perform these surgeries is expected to be so drastic by 2016 that 50% of those

who need total hip replacements will not be able to obtain them, according to Thomas Fehring, MD, senior surgeon at OrthoCarolina Hip and Knee Center, in Charlotte, North Carolina.¹³ Reasons for this shortage have to do with the continuing downward spiral in reimbursements and the lifestyle choices of younger surgeons.

Dr. Fehring states, "The shortage of hip and knee surgeons reflects the economic disincentives for performing total joint replacements. Reimbursement by Medicare for these procedures has fallen significantly in recent years. As a result, most young orthopaedic surgeons are shying away from joint replacements, and are instead going into more lucrative specialties, such as sports medicine and spinal surgeries."¹³

According to the American Academy of Orthopaedic Surgeons, those who do have the surgery, a primary total hip replacement will cost approximately \$40,000 and a secondary revision will cost about \$50,000. These figures do not include costs associated with rehabilitation services following the surgery and adaptive changes made to one's home.

Several studies have investigated the impairments and function in patients with hip OA, such as lower extremity muscle strength, hip range of motion (ROM), and aerobic capacity. Although surgery is very effective

once conservative measures have been exhausted, it is important to note, data indicate that only 12% of the patients seeking help for hip pain ended up having hip replacement within 3 years and 22% within 6 years. Therefore, the patient group *not* candidates for surgery represent the majority of patients seeking primary care for hip pain, including patients with hip OA.³⁶

Research Conclusions

There are 6 main conclusions to be drawn from this research as described in this paper:

1. There is, and will continue to be, a massive increase in the number of individuals suffering from OA secondary to aging and obesity.
2. More and more active and younger individuals are seeking treatment earlier. More than 50% are younger than 65.
3. There is a huge financial burden to the individual and federal healthcare system with over \$100 billion dollars already spent per year on OA treatment.
4. The majority of individuals (78%) seeking treatment for hip pain will not actually need surgery within 6 years, but will need some form of conservative treatment like physical therapy. However, there will still be a huge increase in the number of individuals requiring hip replacement surgery due to the increasing prevalence of hip OA overall.
5. There will be a significant shortage of surgeons to perform these surgeries in the near future due to decreasing reimbursements by payers. The payers will need to move towards a more evidence-based model as stated earlier or there will be a greater expenditure by the payers on narcotics/NSAIDS and other treatments.
6. Combining a variety of Manual Therapy techniques such as Long Axis Hip Traction and Therapeutic Exercise shows the greatest promise for effective and conservative treatment of Hip OA.

There is currently, and will continue to be, an enormous demand for any conservative treatment that can provide positive treatment outcomes while reducing costs for the patient, insurer, and federal government.

Manual Therapy at Home

Hip OA is progressive and the patient's hip will eventually begin to worsen after discharge from the clinic even with the home exercises. They cannot continue with manual therapy in the clinic indefinitely due to costs and limits on the number of treatments by insurance companies. Up to this point, there have not been any effective methods for performing manual therapy at home that are safe, effective and easy to set up by the individual. What if patients were able to add some independent manual therapy to their home program as they had when they were in the clinic? Would they be able to improve and maintain their range of motion, functionality and pain levels even longer? After all, research has already proven that manual therapy in the clinic plays a vital role in the positive treatment outcomes. Why would we not want manual therapy to continue as long as possible?

Introducing the HipTracTM

The HipTrac is a durable, portable, and light-weight hip traction device that is easily and independently used by the patient at home. It replicates the clinical hands-on technique of Long Axis Hip Traction that has been proven effective in providing pain relief as well as maintaining and improving mobility for the patient. Because most individuals that require use of this device will range from 30-90 years old, it was important to have a design with the idea that it had to be extremely portable and simple to use, without the assistance of another person.



The HipTrac is safe, effective, and empowers the individual to work independently towards their own well-being. It has been cleared by the FDA for immediate use and sale beginning in 2012. The clinical manual technique, that it replicates exactly, is used in all medical, physical therapy and chiropractic clinics across the world to decrease pain and generally increase hip mobility.

As stated earlier, beginning conservative treatment with manual therapy by a health care provider, such as a physical therapist, works best by accumulating the effects 1-2 x per week for 3-8 weeks. The patient's mobility increases from one visit to the next, however there is a slight rebound or stiffening between visits. This is normal and occurs regularly at varying amounts depending on the individual. Using the HipTrac, at home

between visits and after discharge, will continue the capsular mobilization and stretching, lessening the rebound effect and decreasing pain. This will lead to improved outcomes sooner and more comfortably.

After discharge, it will allow the individual to have some of the same combination of manual therapy and therapeutic exercise they had while in the clinic that led to their improved outcomes in the first place.

A way to think about manual therapy and the HipTrac is similar to what happens when your car breaks down. You need to push your car off the street and down to the mechanic. It takes a lot of energy and specific force to get the car moving, but once you get it moving, it takes much less energy and specific force to keep it moving. Likewise for hip OA, it is best to see your healthcare provider to get your hip moving, then use the HipTrac with your independent home exercise program to keep it moving after discharge from a formal program.

The HipTrac is not going to eliminate the need for surgical intervention. The hip will continue to worsen no matter what treatment is provided. This newer and better care will simply improve the level of conservative care and quality of life during the natural gap between diagnosis *and* surgery. Most individuals are told by their orthopedic surgeon that they definitely have a hip OA problem, but are not bad enough for surgery yet. During this period of time, of 1-6 years, is when patients reduce their activity level increasing their risk for expensive and life-threatening co-morbidities. Individuals can improve their functionality and quality of life prior to surgery, thus leading to improved physical health eliminating risk for these co-morbidities, reducing medication usage and better preparing individuals for surgery when that times comes.

The idea of a home traction device for treating various orthopedic conditions is not new. There are tens of thousands of home Cervical and Lumbar Spinal Traction units disbursed every year in the United States for treating OA of the spine as well as a myriad of other spinal conditions. They are popular in the medical community and routinely covered by most insurance plans, including Medicare.

Similarly, the HipTrac will help provide the same opportunity to the millions of Americans who are suffering from OA of the hip. What differentiates the HipTrac from the spinal traction units in superiority for its intended use, besides the location of treatment, is the fact that it works on a specific problem; capsular restriction and pain at the hip joint. Spinal

traction units are popular but they cannot be used for every cervical condition because they cannot exactly replicate manual traction by the provider in all cases. Oftentimes, there are slight variances and tweaks to how the provider has to manually traction the spine. The home spinal device cannot do this and therefore the patient may not obtain relief. This will lead to poor compliance at home in some cases.

However, the HipTrac does replicate the manual technique at the hip exactly the way the provider does it in clinic. This is why the insurance company and healthcare system will see greater compliance with the HipTrac for its intended purpose versus the spinal traction units overall.

Current statistical analysis shows that there are already 18-24 million individuals in the United States alone with some form of personal disability related to hip osteoarthritis. The oldest of the “baby boomers”, which consist of 79 million individuals, turned 65 years old beginning January 1, 2011. In 2031, when the oldest will turn 85 years old, there will still be 51 million “boomers” remaining.⁴³ With these staggering figures predicted in the next 20 years and the healthcare crisis that we are already facing, it is imperative that we create or expand any evidence-based, conservative treatment that can help improve outcomes and patient quality of life, while decreasing overall healthcare costs. The HipTrac is designed to do just that.

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