Review Article

Economic Impact of Congenital/Acquired Talotarsal Joint Dislocation and the Role of Extraosseous Talotarsal

Stabilization

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Abstract

Musculoskeletal disorders are the leading cause of disability worldwide and the cost to treat these disorders

continues to rise every year. The pain associated with muscular disorders results in decreased activity for those

affected. Failure to properly treat musculoskeletal disorders can lead to the onset or exacerbation of existing

secondary health-related diseases associated with decreased activity including diabetes, obesity, hypertension, heart

disease, and osteoarthritis, which are also associated with increased healthcare costs. The foot, as the foundation of

the body, must be properly aligned and/or balanced for the entire skeletal kinetic chain to function properly.

Congenital/acquired talotarsal joint dislocation (TTJD) leads to an imbalance and misalignment of joints along the

entire kinetic chain, ultimately leading to musculoskeletal disorders, pain, and comorbidities associated with a

sedentary lifestyle. Conservative treatment of TTJD with orthotics is often ineffective due to poor patient

compliance, and does not address the underlying cause of the pain associated with TTJD. Women are also less

likely to use orthotics due to incompatibility with certain shoe styles. Invasive reconstructive surgery for the

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treatment of TTJD is associated with a risk of complications and a long recovery time. In contrast, extraosseous talotarsal stabilization is a minimally invasive procedure with few complications, and Type II implants have a less than 6% removal rate. Extraosseous talotarsal stabilization could serve as an important link in eliminating the underlying etiology of many chronic musculoskeletal deformities and, in the process, allow patients to maintain normal levels of activity to help combat the development of secondary health-related diseases associated with a sedentary lifestyle.

Keywords: congenital/acquired talotarsal joint dislocation; extraosseous talotarsal stabilization

Economic Burden of Musculoskeletal Disorders

Musculoskeletal disorders, which include pathologies affecting the bones, ligaments, joints, tendons, and muscles, are the leading cause of disability globally. In the United States, these disorders account for over 40% of the disabling conditions of adults aged 18 years and older and more than half of all chronic conditions in people 50 years of age and older in other developed countries age and older in other developed countries and more than twice than that of chronic circulatory conditions and more than twice that of all chronic respiratory conditions. In 2008, one or more symptoms of musculoskeletal disease were reported for 110,340,000 individuals in the United States [1]. Despite these facts, far too little attention is being paid to preventive measures in addressing these progressive pathologies.

The economic impact of musculoskeletal disorders is overwhelming. In 2004 in the United States, the sum of the direct healthcare costs and indirect expenditures in lost wages for treating these disorders was estimated at \$849 billion, or 7.7% of gross domestic product ^[4]. The average annual direct cost for the years 2004 through 2006 was \$576 billion. The burden of these conditions is expected to escalate due to the aging population and sedentary lifestyles of many Americans.

Worldwide, another contributing factor to an increased economic impact of musculoskeletal disorders is reduced childhood mortality ^[5]. Research shows that 1 of 2 people will develop some form of musculoskeletal disorder, and 7 of 10 persons 75 years or older will report 1 or more symptoms associated with musculoskeletal disorders ^[1]. Although the mortality directly attributed to musculoskeletal conditions is low, secondary diseases create a vicious cycle whereby the affected individual becomes increasingly sedentary due to the pain experienced during weight-bearing activities. Increased inactivity, in turn, causes individuals to become more susceptible to other diseases, such as obesity, cardiac conditions, and diabetes.

The Global Burden of Disease study evaluated the economic burden of 291 diseases and injuries in 187 countries and 21 regions of the world for the years 1990, 2000, and 2010. According to the Global Burden of Disease 2010 study, low back pain causes more disability (assessed as years of life lived with disability) than any other condition and is sixth in overall burden (assessed as disability-adjusted life years)^[6]. Results from that study show that musculoskeletal disorders (defined in the study as osteoarthritis, low back pain, neck pain, rheumatoid arthritis, and gout) are the second most common cause of disability worldwide, and these conditions are

estimated to have increased 45% from 1990 to 2010. In addition, these disorders are expected to rise secondary to aging, the increased sedentary lifestyles of individuals, and the associated increases in obesity^[7]. In the Global Burden of Disease 2010 study, musculoskeletal disorders without explicit definitions where placed in an "other musculoskeletal disorders" category, which included autoimmune and other inflammatory disorders such as systemic lupus erythematosus, ankylosing spondylitis, psoriatic arthritis, and a wide range of other joint and muscle problems that cause pain^[5]. In 2010, this "other musculoskeletal disorders" category ranked sixth in disability and was ranked 23rd in overall burden, an increase from a rank of 29th in 1990^[5]. Of the 291 conditions investigated in the Global Burden of Disease 2010 study, hip and knee osteoarthritis was ranked as the 11th highest contributor to global disability and 38th in overall burden ^[8].

Using data from the National Center for Health Statistics' 2012

National Health Interview Survey, the United States Bone and Joint

Initiative, in collaboration with other organizations, assessed the burden of musculoskeletal diseases. In the United States, the leading musculoskeletal-related complaint is back pain, with 62 million adults reporting symptoms in 2008, followed by knee pain with 39 million adults^[4]. Seventeen million adults aged 18 years and older reported that they have difficulty performing routine daily activities without assistance, due to their musculoskeletal complaints ^[4].

One reason that the direct treatment for musculoskeletal disorders is so costly is because the overwhelming majority of treatment options, even surgical correction, fail to resolve the symptoms. Even after back or joint replacement surgery, there are a considerable number of patients who require revision or repeated procedures. "Failed back

surgery" has its own medical diagnosis code. There are primary common procedural codes for revision of back, knee, and hip surgeries. Patients undergoing knee and hip replacement are often warned that the new joint will only last 10 to 15 years, at best. With this in mind, something must be done to address the increasing prevalence of musculoskeletal concerns and to lower the failure rate of treatment.

Indirect Costs Resulting from Musculoskeletal Disorders

Work loss is one of the greatest sources of quantifiable indirect costs associated with musculoskeletal disorders. In a 2008 study, the total number of days individuals spent in bed due to back pain, which was further analyzed for lost work days, was reported^[1]. Fifty percent of participants said that back pain caused them to have days of complete inactivity. The numbers are staggering: the study showed that a total of 671.1 million days were spent by patients in bed due to back pain in 2008, with an estimated 385 million work days lost.

Quality of life is more difficult to quantify in terms of indirect costs associated with musculoskeletal conditions. However, an individual's inability to participate in the activities he or she finds enjoyable and meaningful is a realistic concern with tangible associated direct and indirect costs and consequences.

There are many comorbidities associated with a sedentary lifestyle. Patients with musculoskeletal pain are not rewarded for being active. This is where the cycle begins. These patients suffer as a result of activity; therefore, they become inactive to minimize the pain. Inactivity leads to decreased metabolism of carbohydrates so the body stores this energy as adipose tissue. Eventually, weight gain occurs to the point where patients become obese. Obesity then sets the stage for other medical conditions such as diabetes, hypertension, coronary

artery disease, and even certain forms of cancer^[9]. Patients are then told to control their diets, which, when done as a stand-alone treatment option, is rarely successful^[10]. The missing ingredient is exercise and an increase in general activity level. Patients with musculoskeletal disorders try, but the reward for their effort is pain, so they cease activity. Consider the cost of treating diabetes (\$245 billion) ^[11], hypertension (\$55 billion) ^[12], coronary artery disease (\$108 billion) ^[13], and obesity (\$210 billion) ^[14]. The importance of increasing weight-bearing activity cannot be underestimated.

Congenital/Acquired Talotarsal Joint Dislocation

The musculoskeletal system is a closed kinematic chain. An imbalance, or misalignment, from certain pivotal joints can lead to an imbalance in the entire kinematic structure, ultimately leading to a shift in the balance of forces within the closed system of articulations. The foot, as the foundation of the body, must be properly aligned and/or balanced for the system above to function properly. Often a patient with a musculoskeletal condition proximal to the foot finds that the pain worsens during or after standing or walking. Even without examining the underlying cause, this would seem to be a strong indication that the biomechanics of the foot may play a factor. The single most important structure that determines proper foot alignment with regard to the proximal musculoskeletal chain is the talotarsal mechanism^[15,16]. The talotarsal mechanism comprises the talus, calcaneus the navicular, and the joints formed by the interaction of these bones. Taken together, this mechanism acts as a torque converter, transforming forces both from the body above and from the ground below^[15-17]. When this mechanism is out of alignment, a myriad of pathologies may ensue.

Recurrent talotarsal joint dislocation (TTJD) is a dynamic single or

multi-plane deformity characterized by talar displacement medially, and/or plantarly and/or anteriorly, depending on the plane(s) of dominant motion. The partial dislocation occurs to some degree with all weight-bearing activity. This dislocation deformity results in a shift or redistribution of the weight-bearing transfer of forces throughout the foot^[18]. Moreover, as the talus displaces off the articulating surfaces with these other bones (calcaneus/navicular), excessive tibial internal rotation and knee flexion will occur ^[17,19-22].

An excessive pronatory motion within the talotarsal joint leads to a prolonged internal rotation of the leg, which transmits abnormal forces to the upper kinetic chain resulting in medial knee stresses and lateral dislocation of patella over the femur (Figure 1) [17]. The chain reaction includes compensation at the pelvis, back, and even the neck and skull^[17,23-30]. The resulting osseous misalignment forces a compensatory reflex mechanism to occur making certain muscles, ligaments, tendons, and other soft tissues work harder than they should, while others are underutilized and lose strength and elasticity [31-35]. These compounding destructive events continue to take their tollon the soft tissues with every step taken until the critical threshold

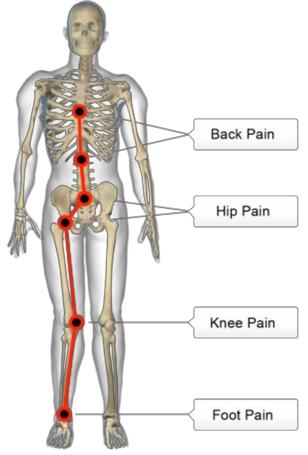


Figure 1. Illustration of abnormal forces to the upper kinetic chain.

is reached and a problem occurs. TTJD is attributed to the development of signs and symptoms of abnormal function localized to the knee^[17,23-26,29,30], pelvis^[17,24,26,27,29,30], spine^[27,29,30,36], neck^[29], shoulder^[29], and even the temporomandibular joint^[29]. The first symptom, pain—an early warning signal—generally occurs at the weakest link in the person's musculoskeletal chain. Unfortunately, medical attention is usually directed at pain relief rather than specifically addressing and eliminating the underlying cause of the condition. How often will an orthopedic surgeon look at weight-bearing foot x-rays or watch the patient walk?

Diagnosis of Talotarsal Joint Dislocation

A diagnosis of TTJD is made by non-weight-bearing and weight-bearing examination in combination with gait analysis, and confirmed on weight-bearing radiographs.

The non-weight-bearing examination of the talotarsal joint is accomplished via range of motion testing—positioning the talotarsal joint through pronation and supination. A normal, stable, talotarsal joint should only have a slight amount of pronation (3 ° to 5 °) (Figure 2). Pronation greater than 5 ° is the first clue that the patient may have a partial dislocation deformity. A typical static weight-bearing examination will show signs of a balanced talotarsal joint. A bisection of the lower leg is parallel to the bisection of the second metatarsal of the foot (Figure 3). A medial bend in these 2 lines also gives another

articular facets. The dynamic weight-bearing examination (gait cycle analysis) can reveal the "too-many-toes" sign, abductory twist, or medial bulging of the talar head (talar ptosis).

Weight-bearing radiographs provide objective, repeatable, non-biased data as to the alignment or dislocation of the talotarsal joint. The primary x-ray views that show this deformity are the dorsoplantar and lateral views. The talar second metatarsal angle on the dorsoplantar view should be less than 16°, with ideal TTJ alignment 3° to 6° [37,38]. A talar second metatarsal angle greater than 16° on the dorsoplantar view reveals a transverse plane dislocation deformity. The talar declination angle on the lateral view should be less than 21 d39]. A value greater than this would be indicative of a sagittal plane deformity.

Treatment of Talotarsal Joint Dislocation

When a patient is diagnosed with a misaligned hindfoot, typically little is done to correct it. There is often a misconception that a misaligned hindfoot is "asymptomatic," and therefore does not require intervention; however, as has been established, a talotarsal dislocation may be causing "symptoms" elsewhere in the musculoskeletal chain.

Conservative Treatment

Traditional treatment options for a misaligned hindfoot structure were to "watch" the problem or prescribe the use of an arch support/foot

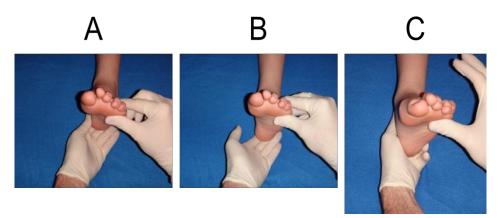


Figure 2. Non-weight-bearing range of motion test of the talotarsal joint (TTJ). (A) TTJ neutral position, (B) normal max pronation, and (C) TTJ dislocation (> 5 ° of pronation).

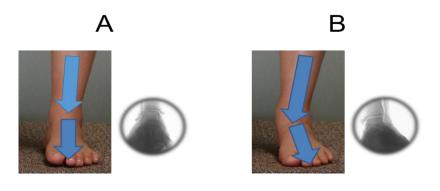


Figure 3. Anteroposterior view showing an (A) aligned and (B) misaligned hindfoot due to talotarsal joint dislocation.

Table 1. List of Evidenced-base Results of Type II EOTTS Device in Treating Recurrent Talotarsal Joint Dislocation.

Decreases anterior forces acting on the medial column of the foot^[18]

Decreases strain on the medial band of the plantar fascia by 33%^[34]

Decreases strain on the posterior tibial tendon by 51%^[82]

Decreases pressures within the porta pedis and tarsal tunnel^[59]

Decreases strain/elongation of the posterior tibial nerve^[33]

Normalizes sagittal plane TTJ dislocation deformity^[54, 83]

Normalizes transverse plane TTJ dislocation deformity^[54, 83]

Normalizes plantar foot weight-bearing forces^[84]

Demonstrates higher success rate over Type I EOTTS devices^[53, 57]

Shows an increase in quality of life^[57]

Demonstrates positive functional outcome scores^[57]

TTJ = Talotarsal joint; EOTTS = Extraosseous talotarsal stabilization.

orthosis, and/or suggest the use of special shoes. As the deformity progressed or caused more localized symptoms, surgeons would recommend rearfoot reconstructive surgery, such as osteomies and/or fusions to realign the bones, and tendon transfers. The problem with continued observation is that while standing, walking, or running, the excessive pathologic forces continue to act on the various soft tissue and osseous structures of the body, leading to progressive destruction. While arch supports are relatively easy to use and do not result in surgical complications, questions remain regarding the effectiveness of a foot orthoses in realigning and maintaining stabilization (and therefore halting destructive forces acting distally and proximally) of the pathologic misalignment of the talotarsal mechanism^[40-48]. Orthoses are a good treatment option for many disorders, but they are not effective for realigning the talus on the tarsal mechanism (Figure 4).

Orthoses are typically designed to work by altering the weight-bearing surface, elevating and supporting the medial longitudinal arch^[49].

Orthoses often result in temporary relief of symptoms and improvement in function while they are being utilized; however, the results depend greatly on patient compliance and use of proper shoes. In 1 study, the use of an arch support was range in price from \$250 to \$600 per pair and typically last 1 to 2 years. Over the course of several years of use by a patient, this represents a major investment. Many people self-diagnose and try various over-the-counter inserts, spending more than an estimated \$1 billion per year on shoe inserts. These inserts typically do little to help, and can even create additional problems as they are often dispensed by nonmedical professionals who cannot properly evaluate patients. While people continue to think that these over-the-counter devices are actually helping their feet, excessive abnormal forces continue to strain their tissues until these tissues ultimately fail. Once a supportive tissue such as a ligament or

tendon loses its function, an additional strain is placed on other soft

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tissues that compensate for the abnormality.

If the osseous misalignment is not controlled, in addition to the continued pathologic forces acting throughout the body, the risk is that what was once a mild deformity will worsen, limiting treatment options. These now major deformities may require the physician to resort to reconstructive surgery options, such as tendon transfer, calcaneal osteotomy, and arthrodesis of the hindfoot bones. These surgeries are associated with a very long recovery and can result in many potential complications and risks for the patient. When surgical intervention is used, the direct costs of the surgery are very high, not taking into account the indirect costs of follow-up care or direct costs associated with surgical failure, including infection, need for revision, or other complications or failure to resolve the presenting complaint.

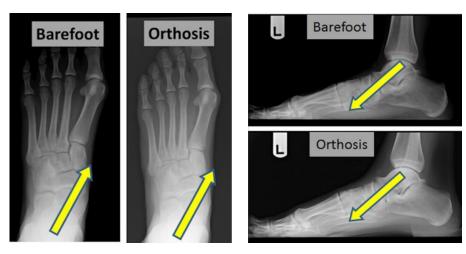


Figure 4. Weight-bearing radiographs of talotarsal joint with no intervention (barefoot) and with custom foot orthosis.

Minimally Invasive Surgery: Implants

A less well-known solution and perhaps better option to correct many problems is extraosseous talotarsal stabilization (EOTTS). This procedure involves the insertion of an internal fixation device that is both extraosseous (not inserted into a bone), and extra-articular (located outside of a joint). This device, known as a sinus tarsi stent, maintains the articular facets of the talus on the calcaneus and navicular specifically at the cruciate pivot point or axis point of talotarsal joint motion^[18]. Subtalar arthroereisis, talotarsal joint blocking/limiting, has a long evolution in design and materials since its first description in the 1940s^[51]. There are 2 main types of sinus tarsi devices currently used (Figure 5) [52]. Type I arthroereisis devices have primarily been used in pediatric and geriatric patients, typically in combination with other surgical procedures. Multiple published reports on Type I arthroereisis devices have identified a rather high removal rate, reported as high as 38% to 100% [53,54]. The limitations, restrictions, and complications of the Type I device led to the next generation of extraosseous, extra-articular talotarsal stabilization devices, Type II non-arthroereisis devices. Type II devices have been shown to be effective as a stand-alone procedure in clinical studies, showing anatomic improvement on radiographs and by subjective reports by patients [55-57].

The Type II sinus tarsi stent is comprised of lateral conical and medial

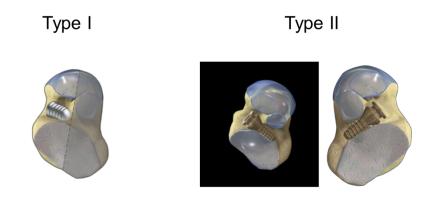


Figure 5. Schematic of talus with the position and location of Type I and Type II extraosseous talotarsal stabilization implants^[4].

cylindrical geometry, matching the anatomy of the sinus and canalis tarsi^[58]. It is inserted in the natural orientation of the sinus tarsi, by anterior-distal-lateral to posterior-proximal-medial positioning. The leading anterior edge is inserted medially beyond the longitudinal talar bisection, stabilizing the TTJ at the cruciate pivot point of talotarsal motion. The stent maintains the congruent alignment of the facets of the talotarsal mechanism, allowing for the normal amount of triplane helicoidal motion^[18]. The placement of the stent does not involve any alteration of bone and is joint-sparing. Studies have shown that the placement of Type II stent normalizes joint forces^[18]; decreases strain on the posterior tibial tendon [33], posterior tibial nerve [33], and plantar fascia [34]; and decreases pressures within the tarsal tunnel and porta pedis^[59], among other improvements (Table 1). Moreover, radiographs have shown normalization of pathologic angles within the foot (Figures 6 and 7) without overcorrection and/or creating new pathologies^[54]. Also important is the removal rate, which, as previously stated, is less than 6% [53,57].

An important concern voiced by patients with any treatment/surgical procedure is the amount of time he or she will lose from work. Some surgical procedures require patients to remain on a non-weight-bearing regimen for up to 8 weeks, whereas patients who undergo the EOTTS procedure with a Type II device can to bear weight on their treated foot immediately, as tolerated and at the

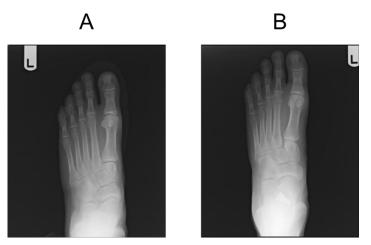


Figure 6. Weight-bearing dorsoplantar foot radiographs of a patient exhibiting talotarsal joint dislocation (TTJD) with a transverse plane deformity (A) before correction and (B) after insertion of an extraosseous talotarsal stabilization Type II implant. Stabilization and normalization of the transverse deformity is shown.

surgeon's discretion. Most patients are able to walk for exercise by 4 weeks and can run or jog by 8 to 10 weeks.

EOTTS, for select patients when indicated, is a rather simple surgical procedure, compared with traditional hindfoot reconstruction, and is relatively inexpensive, especially when compared with treating associated pathologies. Research suggests that patients treated with EOTTS are able to walk and exercise without pain after the correction and, as a result, they may be motivated to increase their activity, which will, in turn, help increase their metabolism, decrease their weight, and lower their blood pressure and blood sugar levels ^{58,60-64}.

Cost of Treating Talotarsal Joint Dislocation

A misaligned hindfoot structure has long been recognized for its potential destructive impact to the entire body^[22,27,28,65,66]. Unfortunately, this fact seems to be frequently overlooked or ignored when patients present with musculoskeletal complaints. Little attention is paid to the cause/effect mechanism and the adverse outcomes associated with the failure to treat this condition.

The current standard of care for musculoskeletal disorders calls for conservative methods to be attempted before any surgical intervention.

Typical "non-surgical" modalities include rest and use of ice, oral anti-inflammatory medicines (over-the-counter or prescription),

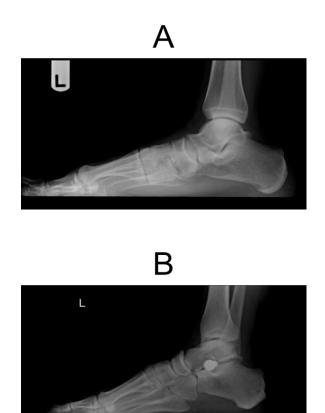


Figure 7. Weight-bearing lateral radiographs of a patient exhibiting talotarsal joint dislocation (TTJD) with a sagittal plane deformity (A) before correction and (B) after insertion of an extraosseous talotarsal stabilization Type II implant. Realignment and stabilization of the sagittal plane deformity is shown.

topical remedies/creams, physical therapy, splints, wraps, braces, orthoses, and immobilization (i.e., removable or non-removable casts), when required. Although seemingly "low-cost," cost factors are compounded over time. The costs of prescription drugs (up to hundreds of dollars a month and often prescribed for an indefinite period), physical therapy (as much as \$30-\$150 per visit, extending over several weeks to months), and braces/splints/casts can quickly add up. Moreover, if the primary disorder is not addressed, the progressive disease process remains unchecked, even if direct symptom relief is obtained for a time. The uncorrected osseous hindfoot misalignment continues to create wear and tear with all weight-bearing activities. Considering that the average person takes 5000 steps a day and over 80,000,000 steps after 45 years of walking, it is only a matter of time before more aggressive surgical intervention is required.

In any given year, about 85% of persons with musculoskeletal diseases make at least 1 ambulatory care visit to a physician's office,

averaging about 6 such visits per year. Fifty-two percent of all people with musculoskeletal diseases will also seek consultation with non-physician ambulatory healthcare providers, including physical therapists, occupational therapists, chiropractors, social workers, physician assistants, nurse practitioners, and other related healthcare workers—with an average of 3.8 annual visits reported for the period of 2002-2004. Also, 83.5% of people with a musculoskeletal condition will fill an average of 18.6 prescriptions each. Computed in 2004 dollars, the mean annual prescription cost per person was \$1196

Specific conditions have been directly attributed to the partial

Cost of Addressing Secondary Pathologies

dislocation of the talus on the tarsal mechanism. Distal pathologies include plantar fasciopathy^[67-76], progressive posterior tibial tendon dysfunction [36,74,77], hallux abducto valgus [36,74], hallux limitus/rigidus [78], metatarsalgia^[74,79], syndrome^[79], hammertoe plantar intermetatarsal neuroma^[36,79], tarsal tunnel syndrome^[59], degenerative joint diseases of the foot and ankle^[79,80]. Surgical treatment of distal pathologies can be quite costly and may involve the use of non-weight-bearing immobilization devices and/or physical therapy sessions for an extended period post-treatment, leading to large increases in direct and indirect treatment costs. Most specialists or surgeons just accept the fact that any successful treatment of non-traumatic disorders at these proximal or distal regions is temporary before recurrence/failure of the primary procedure. Unfortunately, most specialists/surgeons are truly unaware of the recurrence rate of these secondary deformities. This is because it is unlikely that patients will return to the same specialist/surgeon if they become dissatisfied with the progress, develop a complication, or the condition returns; these patients will likely seek the medical care

of another practitioner instead. Therefore, specialists/surgeons may believe that the patient is satisfied with treatment, otherwise the patient would have returned for a follow-up consultation or for more treatments.

Revision surgery on the foot, knee, hip and back is usually more costly than the surgery performed originally. Patients who undergo revision surgery are at greater risk of experiencing complications and are subject to longer recovery periods. Revision total hip replacement, for example, is followed more frequently by complications than primary total hip replacement, with risks of death, dislocation, and infection at rates of 2.5%, 8.3%, and 1.0% respectively^[81]. The cost and risks are compounded by the need to remove any hardware used in the previous surgery.

Conclusion

The economic burden of musculoskeletal diseases continues to grow at an enormous pace. According to the Global Burden of Disease 2010 study the prevalence of musculoskeletal diseases increased 45% from 1990 to 2010^[7]. The connection between talotarsal joint instability as the underlying condition to many secondary musculoskeletal deformities has been established and cannot and should not be ignored. The feet are the foundation of the body: there is a direct link between foot alignment and the alignment of the knees, hips, and back. If medical attention is limited to amelioration of pain or it merely addresses the secondary site(s)/symptom(s)without eliminating the true source, then the symptoms will continue to reoccur. Early intervention is crucial to stop the pathologic progression of the disease process. Contributing authors to the Global Burden of Disease study agree that it is important to seek strategies to reduce hip and knee osteoarthritis through primary and secondary prevention programs ⁸.

The EOTTS procedure should be considered a conservative surgical option and implemented as one of these strategies. The EOTTS procedure can be performed in children and adults. Because pediatricians often encounter the early stages of talotarsal instability, it is imperative that they are educated on the importance of correcting the condition. Early intervention could potentially save millions of dollars in healthcare costs and improve the foot function and the quality of life of these patients compared with delaying treatment until after disease pathology has progressed significantly.

The increasing economic impact of musculoskeletal diseases can be alleviated by considering and using preventive measures that have a strong evidence base of effectiveness. The best and most proven method for addressing abnormal hindfoot motion is EOTTS. As a minimally invasive and reversible procedure, EOTTS should be considered a conservative surgical option. Complications are few and required patient compliance is minimal. A minimal patient investment now may prevent escalating "costs" to treat problems year after year, and return the patient to higher levels of functioning and an improved quality of life.

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