Gifford Medical Center Case

## Study 2012

PRESENTING A NEW AFO---Robert R. Rinaldi, DPM, FAAPSM, FACLES

The “Revolution Brace”, designed, manufactured and patented by American Orthopedics Manufacturing Corporation was tested and clinically trialed at the Gifford Medical Center’s Sharon Sports Medicine Clinic in Sharon, Vermont. Gifford Medical Center is a small community hospital in Randolph, Vermont that has been listed as one of the top 100 Critical Care Hospitals in the country. The Sharon Clinic is a freestanding facility dedicated to the treatment of athletic injuries. It houses a physical therapy department, a radiology department with remote image viewing systems linked to the central hospital’s radiologist for stat x-ray consults and interpretations. Healthcare delivery at the clinic is rendered by a team of certified sports medicine and surgical specialists in Chiropractic, Clinical Orthopedics, and Podiatry. The study and clinical trial of the Revolution Brace was as innovative as the brace itself as this AFO was used in an atypical manner and on an uncharacteristic patient population. The Revolution Brace in this trial was used on the athletic and active patient with posterior tendon pathology, deltoid ligament injury, and as a post-operative adjunct to recovery from surgical procedures. The Revolution Brace and its innovative medial adjusting strap is key to success and compliance as this adjusting strap offers not just necessary support to the foot column but comfort in all activities.

The medial sided moveable strap mimics the posterior tibial tendon and biomechanically supports the functions of the medial column of the foot. The adjustable medial suspension system insures patient comfort at all levels of activity. The intent of American Orthopedics Manufacturing Corporation was to produce an AFO that would enhance foot function while eliminating pain and associated disability. The Sports Medicine Department of Gifford Medical Center took on this trial based on the philosophy that the Revolution Brace could bring an adjunct to treatment levels and outcomes for the active athletic patient of all ages. Presently we have 16 patients in the study. They range in age from 25 to 75. There are 12 female and 4 males in the clinical trial.

CASE DISCUSSIONS---A sampling of cases could increase the understanding of how we used the Revolution Brace in a variety of patients. Patients were enrolled in the study based on diagnosis or failure to respond to other conservative treatment regimens. Patients were all actively involved in athletic or exercise programs except one female with chronic inherited vertical talus. This 75 year old patient has had foot disability her entire life. She did not respond to the use of the Revolution Brace and is listed in our statistics as such.

**CASE # 1**---Patient is a 75 year old male presenting with mar fan syndrome, severe mallet toe, third digit, and Stage 2, posterior tibial dysfunction all on the right foot. Both the mallet toe and the PT dysfunction have been present for years and have been resulting in increased athletic disability. Conservative treatment to the mallet toe had failed to offer relief from pain. A laced style AFO had been made for the

patient and this also failed to offer relief from chronic pain associated with chronic tendonitis. The Posterior Tibial Dysfunction had resulted in the patient giving up his passion for playing tennis. The mallet toe pain added insult to injury by creating pain with every step. Corrective surgery was performed successfully on the mallet toe. Following a normal and unremarkable post-operative course a fiberglass tubular cast impression was made of the patient's foot and leg. The Revolution Brace was dispensed and instructions given as to its use. This patient winters in Florida. He picked up the Revolution Brace as he was leaving on his drive south. We made arrangements for telephone consultation to check on his progress. Within one month the patient reported that he was able to resume playing tennis with no pain and no symptoms of stiffness that would be associated with tendonitis after rest.

**CASE # 2**--- A 43 year old female, equestrian, and self- employed with an active landscape design and maintenance business presents with Type Two Accessory Navicular, chronic disabling pain that has now reached a point that she can no longer function without pain scaled by her to "ten out of ten" in sport or work. The patient had been in our practice for several years and had been maintained with injection therapy as well as constant use of intrinsically posted polypropylene orthotics. The patient's history of pain exceeds twenty years. She offers that she cannot recall ever being without foot pain and severe early onset of foot fatigue in athletic activities even from her adolescent years. The disability has now progressed to holding proper form in stirrups while performing even easy horse rides known as a "tack" results in pain.
We felt that the patient could benefit from the use of the Revolution Brace and a treatment plan was created to use the brace until her work and riding season was completed and then perform corrective surgery. The Revolution Brace offered success as planned and the patient was able to complete her season. A Kidner Procedure, excision of the accessory navicular with advancement of the posterior tibial tendon, was performed without complication. Following a three week post-operative period of non-weight bearing in mildly plantar-flexed fiberglass posterior splinting or casts the patient was referred to physical therapy and asked to return to using the Revolution Brace. The use of the Revolution Brace offered early, pain free ambulation and return to normal activities as compared to other patients with similar diagnosis and surgical treatments. At six weeks post-op this patient was capable to returning, pain free, to her horse riding and to light work with the use of the Revolution Brace. At twelve weeks post-op the patient had returned to all activities without restriction.

**CASE # 3**---A twenty five year old male with severe crush injury to the right foot and lower leg was referred to us following open reduction fracture repair of his calcaneus, tibia and fibula. Surgery was considered successful but the patient had difficulty maintaining muscle control of foot resulting in gradual progressive plantar flexion rendering his right limb dysfunctional. His injury occurred in the production of granite in a stonecutting facility locally know as a "Stoneshed". Following examination and consultation with physical therapist we felt that the use of the Revolution Brace could offer relief from pain and also help maintain his foot in a more normal functioning position. He adapted to the use of the REVOLUTION AFO almost immediately and was able to return to gainful employment in the stoneshed. Where other AFO devices had failed to prevent the gradual plantar flexion, or rendered him unable to work within his field of granite production expertise the Revolution Brace allowed him to function more normally. He returned to work and to his passion for motorcycle riding.

**CASE # 4**--- A 70 year old male with complicated total hip replacement requiring additional revision surgery that resulted in a foot drop was registered into the Revolution Brace study. This same patient, though active and exercising, suffered from mild obesity and muscle atrophy secondary to failed hip

surgery. He found the Revolution AFO to be unsatisfactory and we include him as a "failure to respond". This patient may have responded better to an articulating AFO.

**CASE #5---** A 43 year old female runner who had experienced an osteotomy of the first metatarsal for the correction of a Hallux Valgus deformity was referred with chronic pain in the area of the deltoid ligament on the operated right foot. X-ray images display a short first ray secondary to the osteotomy on the first metatarsal. We primarily treated this patient with intrinsically posted polypropylene orthotics with no positive results. MRI diagnosis confirmed stress injury to the deltoid ligament fibers. Injection therapy was attempted including protein rich plasma, PRP, and this also failed to respond with a positive result. The Revolution Brace was fitted to the patient in January 2012 and within one month the patient reports that she is improved. The patient continued to improve throughout a course of five months utilizing the Revolution Brace on a daily basis. She early on returned to the gym for her routine workouts and in May 2012 she reported that she had returned to running without pain. She now uses the Revolution Brace only on occasions when she feels medial sided stress of her right foot. The patient has been discharged.

The Revolution Brace trial began in August 2011; to date we have 16 patients in the program with 14 patients achieving improvement and ability to return to normal activities without pain. The Revolution Brace in all cases was used on an "ad lib" basis and not on a fulltime basis. Once stabilized each patient had been instructed to use the brace if they feel onset of fatigue or if they determine that their activity will be heavy and burdensome.

**CONCULSIONS**---Fourteen out of sixteen patients enrolled in this initial study report that their condition rapidly improved and that they were able to return to an athletically active lifestyle. The clinical trial also leads to the impression that treatment of medial column soft tissue injury in the foot and lower leg will respond best with early use of an AFO. Compliance is key to success. When we compared the Revolution Brace to other AFO models our combined clinical experiences found better patient acceptance with the Revolution Brace and attribute this primarily to the innovative medial adjustable strap. The Revolution Brace allows infinite and easy adjustment by the user and this contributes to a more constant comfort level. Putting on the Revolution Brace is simple and easy; it usually does not require shoe size alteration with some exceptions, and the short plantar plate allows the foot to function with more anatomically correct motion. The Revolution Brace allows the patient to walk, run, climb and bend with very little restriction of motion.

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