# DESIGN SYNOPSIS

AND

# MEDICAL OUTCOMES ASSOCIATED WITH CRUTCH USE

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# INDICATIONS AND RATIONALE FOR USE OF THE ERGONOMIC COLLAPSIBLE CRUTCH

Although material composition has changed, the basic design of the crutch is largely the same as it has been for the last 5,000 years.[8] Crutches have basically been sticks or tree branches with a hand and underarm support. Crutches have been used to assist balance and ambulation. However, they have extracted a price for their use, resulted in significant potential problems for their users, and have not been ergonomically designed. Technology has resulted in significant modifications in tools that are used in the workplace; however, no significant modifications have been brought about in the universal design of the crutch.

Repetitive loads on the hands, wrists, elbows, and shoulders have resulted in injuries secondary to crutch usage.[7,11,20] These injuries are similar to cumulative trauma syndrome as described in the workplace. Many of these injuries are well documented in the medical literature.

Compressive neuropathies in the upper extremity have been well established with the use of the traditional crutch[1,27,29] . Injuries to the suprascapular[25], axillary [29] , radial[17,22] , and ulnar nerves [15,32] have been discussed. Carpal tunnel syndrome has also been described as being a result of crutch usage. An association between the development of carpal tunnel syndrome and the use of assistive devices by patients has been reported [22,23]. In a group of post-polio patients diagnosed with carpal tunnel syndrome, the use of a cane or a crutch was reported to be a risk factor for the development of carpal tunnel syndrome. Repetitive impulse loading combined with wrist extension and radial deviation was suggested as a risk factor associated with assistive devices.

Vascular compromise secondary to the use of axillary crutches has also been well described in the literature. The use of axillary crutches has been reported to result in axillary artery stenosis[9], thrombosis[4,9], development of aneurysms[6], and recurrent embolism[30]. These significant injuries have threatened to compromise the viability of the upper extremity, and have required significant surgical intervention to revascularize the limb to avoid its loss.

Other upper extremity injuries that have been reported have included stress fractures of the ulna[28] as well as avascular necrosis of the humeral head[3,18] and the development of glenohumeral osteoarthritis[19].

The use of crutches has had a significant effect on the energy expenditure and activity intensity of the user[5,10,12,13,14,16,24,26,31]. It has been documented that it takes about twice as much energy to ambulate with a swing-through gait crutch as it does for normal ambulation. The vertical movement that is required of the upper extremities to maintain posture is similar to performing a body push-up with every step. This energy requirement, as well as the body's reaction to the shock of impact, threatens to limit the ambulatory status of the patient. Waters, et al.[34] , evaluated the energy consumption with unilateral non-weightbearing crutch ambulation in a group of 25 newly injured fracture patients. The rate of oxygen uptake was 32% greater than the value for normal walking, the heart rate was 53% greater than normal, and the respiratory quotient was markedly elevated. They concluded, "These findings account for the common clinical experience that the newly injured fracture patient, unable to weight bear on an injured limb and requiring crutches, is a severely restricted ambulator."

So as we can see, although the purpose of the crutch is to allow the injured to ambulate, the cost of doing so can be significant. However, the cost of not remaining ambulatory could be even higher. If patients are unable to use crutches because of acquired injuries to the upper extremity or secondary to a lack of energy, there are significant consequences[2,5,21]. Loss of mobility can result in, but is not limited to, depression, osteoporosis, loss of joint mobility, decreased circulation, increased risk for deep venous thrombosis, increased risk of urinary tract infections, and susceptibility to pressure ulcers.

Therefore, the indication for the use of this present device is to allow the user to maintain mobility, reduce the incidence of cumulative trauma injuries to the upper extremity, and to lessen the energy expenditure requirements.

A. The compression system accomplishes three purposes:

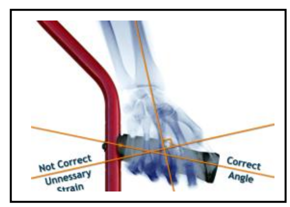

a. Provide spring assisted energy.
b. Reverse the direction of impact energy.
c. Lessen the impact pressure on the body.

i. Spring assisted energy captured through a suspension system is released to provide walking assistance. Energy consumption levels are reduced, allowing patients to ambulate further distances, increasing strength, and reducing rehabilitation time and costs (see attachment 1). Increased ambulation reduces poor outcomes of rehabilitation attributed to non-compliance to ambulation requirements. By reducing non-compliance, rehabilitative success increases, and cost of long term ambulation decrease. Also, patients will not have to go to more expensive devices such as wheel chairs, walkers and scooters.

ii. The unique compression technology reverses impact energy. Upon impact the suspension compresses, collecting static energy, resulting in downward pressure as the elbows extend. This eliminates upward motion, reduces axiliary nerve, skin and muscle damage resulting from a "jamming" of the underarm cradle. Energy reversal prohibits upward motion, alleviating axiliary pressure. When using a crutch with out a suspension, upon impact, the crutch must arc, allowing the underarm cradle to drive upward into the axiliary. This movement is dangerous and results in medical injury (see

Attachment 2). With the compression system closing upon impact, the movement becomes downward. Correct use of the suspension crutch requires that there be enough bend in the elbow so that the elbow extends downward with the compressing of the spring. The shoulders stay level and the patient maintains a straight back, staying in an appropriate posture position. As they begin their stride, they place the tips of the crutch in front of them, move with a level position across the top of the crutch, allowing the suspension to compress and the elbows to extend. The body stays level, avoiding dipping and bending downward. This avoids injury to the back, shoulders and scapula that can be common with crutch use. (See Attachment 3). The result of the technology, combined with the technique defined when using the crutch, totally redefines crutch use, eliminating injury and pain, while positively directing energy to reduce energy consumption by utilizing it to propel the user forward.

iii. The compression system reduces damaging impact energy transferring to the body. The problem with the old crutch is that as patients use it, they are forced into poor posture and ergonomic positions. When entering their strides, they are forced to begin in a downward motion, (hunch over) with their back in a poor posture position. This movement creates downward motion that upon impact reverberates back to the patient's joints, muscles, and nerves. (See Attachment 4). With a compression system, the impact energy is absorbed into the spring allowing the upper body to stay level as the pressure is reduced by the spring mechanism.




B. Handle position is located at a proximate 15 degree downward angle, placing the wrist in the natural position. Positioning the hand and wrist correctly keeps the carpal tunnel open, maintaining natural blood and nerve flow, reducing injuries created by a "kinking" of the wrist, reducing carpal tunnel restriction. This also eliminates repetitive impact damage to the carpal tunnel. Medical studies indicate that for the wrist to be in the natural position, the third metacarpal must be in alignment with the radius bone. (See Attachment 5). With traditional crutch the hand position is forced into a pivot position, "kinking" the carpal tunnel and positioning impact forces onto the carpal tunnel, median and radial nerves. A poor ergonomic position. (See Attachment 6).

C. The underarm cradle is elongated to provide additional support and stability. If the user is unstable the extended underarm cradle provides support. The underarm cradle provides a conscious level of support to the user.

D. The tip is softer and more pliable. The pliability of the tip enhances the ability of the crutch to stay stable against the flat surface. It has a gripping element that is not part of the traditional crutch. The tip does not take the brunt of the impact. The impact is cushioned with the suspension system, allowing the tip to adhere to the surface.

E. A highlighted feature of the crutch is that it folds. The folding design allows for the crutch to be placed in safe places when they are not in use. For patients who travel, they can be easily placed in the trunks of small cars, or in the overhead bins of airplanes. Elderly patients who primarily used motorized scooters or wheel chairs can fold the crutches and put them in a back pack on the back of their scooters.

F. The unique design of the structure allows for the return of natural energy. As the patient maintains a good posture position, the forward momentum of the upper body creates positive momentum for the user.

G. The crutch is made from a high grade, light weight (aircraft) aluminum labeled T6 6061. It is extremely durable, and can withstand repeated use and is anticipated to last for several years. Static, mechanical and end-user testing of the crutches for endurance and strength has been extremely positive. We have documented that a pair of crutches will support persons of up to 400 lbs, and the suspension system has been tested above 800,000 cycles under extreme weight pressure. The crutch has a 5 year warranty, and is expected to last several years beyond that.

The Millennial Crutch is safer, more ergonomically correct, and better for users. The crutch was awarded the 2005-2006 National Merit Award, for Best New Product that MOST IMPROVES THE QUALITY OF LIFE. It is time for our industry to embrace a change.

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