CLINICAL BENEFITS OF THE HANDS FREE CRUTCH (HFC)

EXECUTIVE SUMMARY

It is now well understood that as compared to crutches or knee scooters, the Hands-Free Crutch (HFC) allows patients to perform in their activities of daily living. Less known are the medical benefits, which are now supported by evidence-based research. Comparisons of crutches and knee scooters to the HFC have shown that the HFC provides:

- Increased patient preference – 90% of patients prefer the HFC over crutches or knee scooter
- Increased muscle activity – Crutches and scooters invoke minimal muscle activity of the non-weight bearing limb. With the HFC, both upper and lower muscles of the affected limb are activated in phase similar to unassisted gait.
- Decreased muscle atrophy – Muscle atrophy is reduced when using the HFC as compared to crutches or knee scooters.
- Increased blood oxygen concentration and delivery – Use of the HFC results in higher blood oxygen delivery to the injured limb.
- Improved stability and safety – Users of the HFC are more stable and have fewer secondary mobility device related injuries than crutches or knee scooters.
- Faster recovery - The HFC provides faster recovery than crutches or knee scooters.
- Increased compliance to non-weight bearing recommendations.

Preferred by 90% of Patients

Nine out of ten patients report that they prefer the HFC over crutches according to a peer reviewed article published in the Foot and Ankle International. This study concluded that patients also experienced less discomfort and exertion using the HFC compared to crutches. *See Appendix A.1 for details and citations*

Increased Muscle Activity

A recent study published in the Foot and Ankle Orthopaedics compared the muscle activity for the injured leg of the HFC (HFSC) and crutches (SAC) and concluded that crutches led to near zero muscle activity while the HFC led to muscle firing of the non-weight bearing limb similar to walking gait (Figure 1). This in turn decreases muscle atrophy, improve blood flow and enhanced healing for non-weight bearing lower limb injuries. *See Appendix A.2 for details and citations*

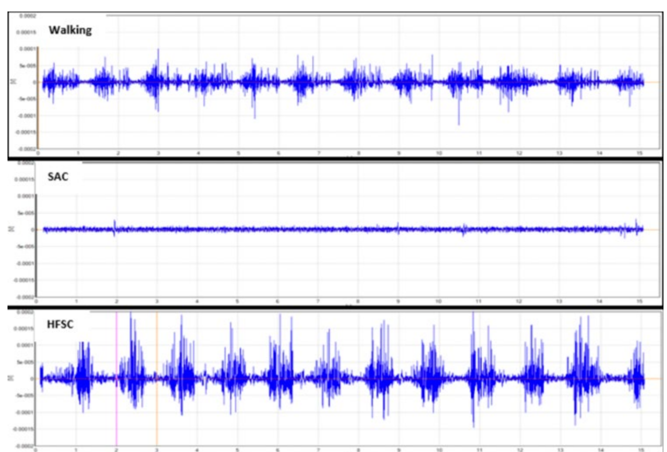

Figure 1: EMG data from the vastus lateralis.

Increased Blood Flow and Decreased Venous Stasis

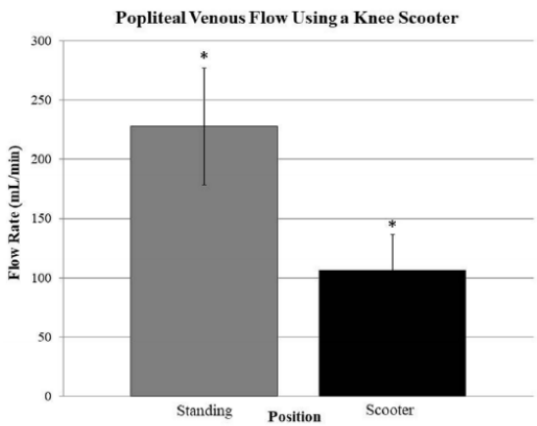

Figure 2: Mean Volumetric flow rate of a knee scooter.

Studies show that knee scooters and crutches reduce blood flow significantly in the non-weight bearing limb (Figure 2) and that declines in blood flow lead to blood clots and pulmonary embolisms. Recent research proves that muscle activity has a major impact on blood flow even more than the knee flexion angle. This counterintuitive result coupled with the results of another study showing that the HFC increases muscle activity in the injured leg has implications in blood flow. A direct study is currently underway to measure the blood flow when using the HFC, knee scooters and crutches. *See Appendix A.3 for details and citations*

Decreased Muscle Atrophy

A large body of scientific evidence suggest that crutches lead to muscle atrophy. The knee flexion angle impacts muscle atrophy due to studies that show that a shortened muscle is more susceptible to atrophy. Because the HFC fixes the knee angle to 90° while this angle is approximately 30° for crutches, the muscles are in a lengthened position with the HFC when compared to crutches thereby suggesting that the HFC will reduce atrophy and strength losses. This conclusion is further supported based on studies that show increased muscle activity with the HFC and muscle activity having a positive influence on muscle atrophy. *See Appendix A.4 for details and citations*

Increased Muscle Oxygen Delivery

Oxygen delivery via blood flow is essential for healing in the injured site. Preliminary data from North Dakota State University shows that the HFC leads to greater muscle oxygen saturation compared to crutches (Figure 3).

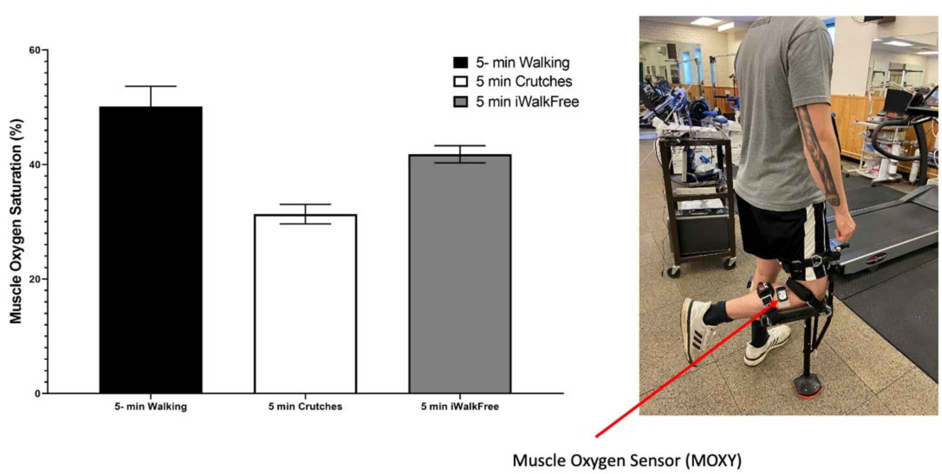

Figure 3: Oxygen saturation of gastrocnemius muscle for normal walking, crutches and HFC.

Improves Stability

A mobility device that improves stability is key to prevent falls and secondary injuries. While studies have shown that knee scooters were associated with falls, a similar association has not yet reported for the HFC. There are 0 injury claims in the entire history of the company that has sold over 100,000 HFCs. A research study is currently underway which uses angular momentum to compare the walking stability while using the HFC versus walking using crutches (Figure 4). *See Appendix A.5 for details and citations*

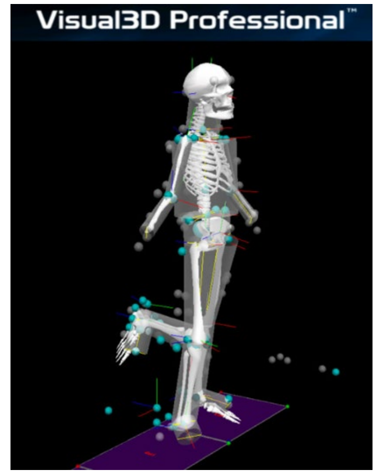

Figure 4: Visual 3D model of HFC user

Faster Recovery, Reduced Healthcare Costs and Faster Returns to Work

Muscle activity, blood flow, oxygen delivery and muscle atrophy impact healing and recovery time for lower limb injuries. Research that supports that the HFC provides improved muscle recruitment, less atrophy and improved oxygen delivery via greater flow will result in accelerated and enhanced healing for patients with lower limb injuries. *See Appendix A.6 for details and citations*

Ability to Perform Day to Day Activities (ADLs)

Routine daily activities are either impractical or not possible using crutches and knee scooters but are entirely possible using the HFC. While it is self-evident, a research study is currently being conducted to directly compare the ability to perform activities of daily living between the HFC, knee scooters and crutches. *See Appendix A.7 for details and citations*.

Elimination of Secondary Injuries Related to Mobility Device Use

Crutches often lead to secondary injuries such as Carpal Tunnel, axillary nerve damage, etc. while these injuries are non-existent with the HFC because it recruits the patient's leg to support their body weight, unlike crutches which use the hands or arms. Published research also report that knee scooter users have a high rate of falling with a large prevalence of scooter related injuries. The HFC has an impeccable safety record with zero reported injuries since its introduction in 2001. *See Appendix A.8 for details and citations*

Increased Patient Compliance

Because activities of daily living are difficult or impossible to do with knee scooters and crutches, non-compliance to non-weight bearing instructions are common and often cause re-injuries that extend the recovery time. The HFC offers hands free mobility and independence which enables ADL's and increases compliance. *See Appendix A.9 for details and citations*

Less Fatigue

Crutches have been associated with higher energy expenditure in prior studies. Published research show that patients experience less discomfort and fatigue using the HFC. Two research studies are currently running tests to measure oxygen consumption while using the HFC, knee scooter and crutches. Assistive devices that lower energy expenditure impact compliance and the ability to perform activities of daily living. *See Appendix A.10 for details and citations*

APPENDIX

A.1 Patient Preference

The HFC is preferred by 86% of foot and ankle patients over crutches (Martin et al., 2019). Patient satisfaction and preference determines the level patients comply to non-weight bearing recommendations (Martin et al., 2019) which is of paramount importance to achieving optimal results and prevent postoperative complications such as wound breakdown, loss of fracture fixation or hardware failure (Chiodo et al., 2016; Gershkovich et al., 2016).

A.2 Muscle Activity

Research proves that the HFC provides statistically significant increases in muscle activity for the hip, quadriceps and calf muscles in the non-weight bearing leg with muscle activity patterns consistent with normal unassisted ambulation in terms of both intensity and activation per EMG recordings (Dewar & Martin, 2020; Sanders et al., 2018). On the other hand, crutches and knee scooters lead to statistically significant reductions in muscle activity in the non-weight bearing leg compared to normal unassisted ambulation (Clark et al., 2004; Dewar & Martin, 2020; Sanders et al., 2018; Seynnes et al., 2008). The heightened level of muscle engagement in the non-weight bearing leg using the HFC compared to crutches could potentially lead to decreased atrophy, increased blood flow and enhanced healing (Dewar & Martin, 2020). Dr. Martin and his team at Creighton Medical rehabilitation science research laboratory are currently performing a head-to-head study evaluating EMG muscle activation comparing the HFC to a standard knee scooter.

A.3 Blood Flow

Using the HFC leads to increased blood flow in the non-weight bearing limb. Research has shown that the HFC provides the greatest muscle activity compared to both crutches and knee scooters (Dewar & Martin, 2020; Sanders et al., 2018) and associated research has shown that muscle activity has a major impact on blood flow while having a larger effect on flow than knee flexion angle (Berlet et al., 2021). This corroborates the findings of prior works which reported a significant decline in blood flow for knee scooters (Ciufo et al., 2018) with crutches leading to the greatest decrease secondary to the static position the leg is held in (Berlet et al., 2021). When poor blood flow continues, it can cause DVT (blood clots) in the lower extremities (Faghri et al., 1997; McLachlin et al., 1960; 1960; 1960) and cause pain venous congestion and life-threatening pulmonary embolisms (PE). It is generally understood that the incidence of DVT is higher for patients with lower limb non-weight bearing injuries than for the general population. Reduced blood flow can also impact oxygen delivery to the injured muscle and bone which is important for healing (Lu et al., 2013). Dr. Hackney at the Department of Health, Nutrition and Exercise Sciences of North Dakota State University is conducting a study to measure blood flow, muscle oxygenation saturation and metabolic cost of locomotion while using the HFC, knee scooter, crutches and normal ambulation. Using 50 participants, the blood flow of the popliteal artery and vein are measured using pulsed wave doppler on a Phillips HD11XE diagnostic ultrasound system and a MOXY sensor is applied to the lateral gastrocnemius, vastus lateralis, biceps femoris and gluteus medius to monitor oxygen saturation levels of the suspended limb. They anticipate having preliminary data later this summer.

A.4 Muscle Atrophy

The heightened recruitment of the muscles in the non-weight bearing leg when using the HFC compared to crutches decreases the level of disuse muscle atrophy (Dewar & Martin, 2020), based on associated research that shows the degree a muscle will atrophy is dependent on the activity of the muscle (Antonutto et al., 1999; Clark, 2009; Clark et al., 2004). This is further supported by prior research that shows a muscle fixed in a shorted position atrophies faster than if a muscle is fixed in a lengthened position (Booth, 1982; Booth & Gollnick, 1983). Thus, the knee flexion angle was shown to play an important role in muscle atrophy (Campbell et al., 2019). Because the HFC fixes the knee angle at 90° flexion which lengthens the muscle, the muscle atrophy after a period of non-weight bearing is expected to be less compared to crutches that fixes the knee angle at approximately 30°. This could partially explain why crutches have been shown to have led to significant muscle atrophy with reductions in muscle size and strength as well as structural changes in muscle fibers in various prior studies (De Boer et al., 2007; Hather et al., 1992; Tesch et al., 2016).

A.5 Stability

Prior studies show that patients feel safer using the HFC (Rambani et al., 2007) and preferred the HFC over crutches (Martin et al., 2019). Well over 150,000 HFC's have been used with zero reported injuries. Historical and voluminous anecdotal evidence support that the HFC leads to stable locomotion. Dr. Wilken, an expert in walking stability and falls in the Department of Physical Therapy and Rehabilitation Science at the University of Iowa is conducting a study that compares the walking stability of the HFC with walking using crutches. The range of angular momentum for both mobility devices are estimated using computerized gait analysis. The objective is to complete the study by the end of this year. In addition to this, Dr. Yao at the Orthopedic Clinic of Hannover is conducting a study that compares the tripping events of the HFC and crutches. Various validated walking tests such as the 10 meter walking test, 6 minute walking test, stair climbing test and timed-up-and-go test are used to count tripping events. Their objective is to complete this study also by the end of this year.

A.6 Recovery Time

A randomized control trial conducted using 80 patients showed that patients were discharged significantly faster after using a HFC compared with using other mobility devices (Rambani et al., 2007). Reductions in muscle atrophy and improvement in blood flow when using a HFC impacts the total recovery time for lower limb injuries with quicker rehabilitation, faster healing and less cases of blood clots (Dewar & Martin, 2020). The increased muscle oxygenation saturation using the HFC via improved blood flow also enhances healing (Lu et al., 2013). Crutches cause reductions in cross-sectional area of the quadriceps femoris muscle of about 0.4% per day (Clark et al., 2004). Because the HFC reduces muscle atrophy, it leads to faster therapeutic gains. In addition to these, secondary injuries as a result of using crutches are nonexistent when using a HFC which also contributes to reducing the recovery times of lower limb injuries.

A.7 Activities of Daily Living

Unlike crutches and knee scooters, the HFC is a hand free mobility device. Thus, activities of daily living (ADLs and IADLs) that are impossible to do with crutches and knee scooters such as shopping, working, cooking, childcare, etc. are possible with the HFC. A randomized control trial with 80 patients with both upper and lower limb injuries showed that they were able to complete activities around the house using the HFC (Rambani et al., 2007) and patients had a more positive attitude to life due to the improved independence with the HFC (Barth et al., 2019). This is just one of the reasons why the HFC has a higher preference rating than crutches (Martin et al., 2019). Researchers Dr. Timmerman and Dr. Reidy at the Department of Kinesiology and Health of Miami University are conducting a study that aims to investigate the ability to perform activities of daily living (ADLs) using a HFC compared to crutches and knee scooters. They will be using the validated Glittre ADL test which includes walking and climbing stairs, while using a portable calorimetry system to show metabolic cost as compared to crutches and knee scooters. They anticipate having preliminary data later this fall.

A.8 Secondary Injuries

Crutches lead to seven-fold increase in the force that runs through the axilla (Rambani et al., 2007). This increased force at the axilla has been shown to lead to secondary injuries such as axillary artery thrombosis (Tripp & Cook, 1998) and crutch palsy (Raikin & Froimson, 1997). Other complications as a result of crutch use are carpal tunnel syndrome (Gellman et al., 1988) and shoulder joint degeneration (Shabas & Scheiber, 1986). Secondary injuries also occur with knee scooters due to the increased risk of falling (Rahman et al., 2020; Yeoh et al., 2017). Because there is no loading of the hands and upper extremity when using a HFC, secondary injuries have not been reported with the HFC.

A.9 Patient Compliance

The HFC improves patient compliance to non-weight bearing restrictions, due to prior research that shows that patients prefer a HFC over crutches and the important role patient preference plays on patient compliance (Martin et al., 2019). In addition to this, because patients are able to function independently using the HFC with the ability to do activities of daily living (Rambani et al., 2007), the HFC will lead to better compliance. Patients with lower extremity injuries have been known to be noncompliant with prescribed weight bearing restrictions (Chiodo et al., 2016; Gershkovich et al., 2016; Kubiak et al., 2013). Lack of compliance leads to complications such as wound breakdown, loss of fracture fixation or hardware failure (Gershkovich et al., 2016).

A.10 Energy Expenditure

Increased physiological demand has been shown to be an important factor in discontinuance and noncompliance to weight bearing restrictions with the use of assistive devices (Bateni & Maki, 2005). Therefore, mobility devices designed to assist ambulation should keep energy expenditure to a minimum while still allowing normal walking speeds. Prior research shows that the physiological demand and exertion are lowest for the HFC compared to both crutches and knee scooters (Kocher et al., 2016; Martin et al., 2019). Crutches lead to lower gait speed and increased rate of perceived exertion (Bhambani & Clarkson, 1989). This is further supported in other prior studies where crutches have significantly higher energy costs compared to normal unassisted ambulation (Dounis et al., 1980; Mcbeath et al., 1974; Nielsen et al., 1990; Sankarankutty et al., 1979; Thys et al., 1996). Researchers Dr. Timmerman and Dr. Reidy at the Department of Kinesiology and Health of Miami University are conducting a study that measures energy expenditure with a portable indirect calorimetry system for the HFC, knee scooter and crutches. Similar to this study, Dr. Hackney at the Department of Health, Nutrition and Exercise Sciences of North Dakota State University is currently conducting a study to take metabolic measures using a portable metabolic analyzer.

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