CLINICAL BENEFITS OF THE HANDS FREE CRUTCH (HFC)

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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 significant medical benefits, which are now supported by evidence-based published 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 and is most favorable among users when completing activities of daily living.
- Ability to perform activities of daily living – HFC users are more functional and are able to do any daily activities they would normally do prior to injury.
- Increased muscle activity – Crutches and scooters both 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 flow – Significant increases in venous blood flow are observed when using the HFC compared to crutches and knee scooters
- Reduced risk of DVT – Muscle activity of the lower leg and measured increases in venous blood flow result in reduction of DVT risk.
- Increased oxygen concentration and delivery – Use of the HFC results in higher blood oxygen delivery to the muscles of the injured limb.
- Improved stability and safety – Users of the HFC are more stable than crutches and have fewer secondary mobility device and fall related injuries than crutches or knee scooters.
- Faster recovery - The HFC provides faster recovery than crutches or knee scooters with faster discharge and returns to work.
- Increased compliance to non-weight bearing recommendations
- Decreased changes in human brain plasticity

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. Another study compared the effect of crutch use with or without a walking boot on patient preference and found that the participants preferred the HFC over crutches in both conditions. Furthermore, several studies suggest that patients experience less discomfort, exertion and pain using the HFC compared to crutches. The ability to perform activities of daily living when using the HFC was shown to be one of many reasons why the HFC is favorable among patients who have to remain non-weight bearing during the recovery of a lower limb injury. *See Appendix A.1 for details and citations*

Increased Muscle Activity

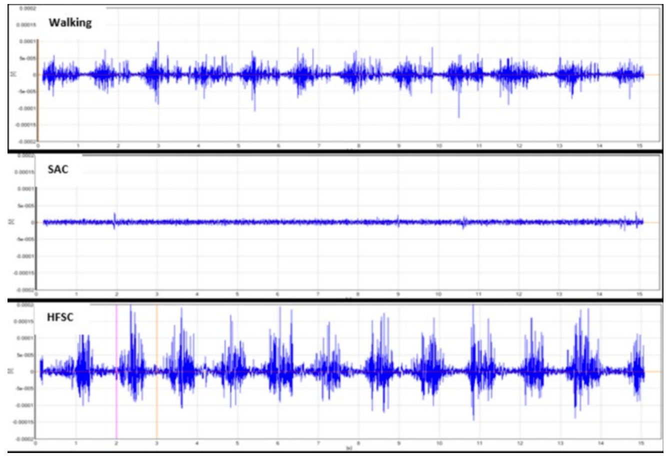

Figure 1 EMG data from the vastus lateralis.

A 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 unassisted walking gait (Figure 1). A subsequent study published in the same journal this time comparing the muscle activity of the HFC with knee scooters demonstrated that HFC again led to increased muscle activity and recruitment consistent with normal walking when compared with a knee scooter. Given that the HFC is the only ambulation device that is able to simulate normal gait and moreover is the only device that is able to generate muscular activity closest to normal walking, the HFC has the potential to meet the unmet need for a mobility device that is able to decrease muscle atrophy, improve blood flow, reduce the risk of developing a deep vein thrombosis (DVT) as well as enhance healing which all have been the disadvantages of crutch usage in various prior studies. *See Appendix A.2 for details and citations*

Increased Blood Flow and Decreased Venous Stasis

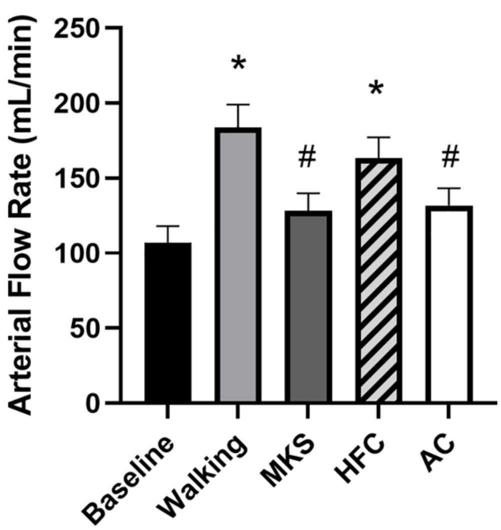

*Figure 2 Popliteal artery blood flow immediately following HFC, knee scooter (MKS) and crutches (AC). *Significant increase from baseline, P<.05. #Significant increase from walking, P<.05.*

A comprehensive study showed that the blood flow following the ambulation using a HFC was not significantly different than normal unassisted walking. In comparison, ambulation using either a knee scooter or crutches led to a statistically significant reduction in popliteal blood flow and vessel dimension. Differences in blood flow between ambulation conditions has implications associated to the prevention of deep vein thrombosis (DVT) and pulmonary embolism. The contribution of this study is significant as it provides evidence to support that the negative effects of knee flexion for a prolonged period of time can be mitigated by the HFC due to muscle activation in the suspended limb. Moreover, this study proved that the increase of muscle pump activity with the HFC compared to both knee scooters and crutches has a direct effect on local blood flow and vessel dimensions even more than knee flexion angle. *See Appendix A.3 and A.4 for details and citations*

Improved Muscle Oxygen Delivery

Oxygen delivery via blood flow is essential for healing in the injured site. A direct study measured the muscle oxygen delivery immediately following the HFC, knee scooter and crutches and compared it with normal unassisted walking. This study concluded that the HFC leads to greater muscle oxygen saturation compared to crutches in both the biceps femoris and lateral gastrocnemius muscles (Figure 3). Furthermore, this study found that there were no significant differences in muscle oxygen saturation between the HFC and normal unassisted walking for both of these muscle groups. The heightened level of muscle oxygen delivery in these muscles groups have significant implications in healing as well as mitigating deep vein thrombosis and reducing muscle atrophy. *See Appendix A.5 for details and citations*

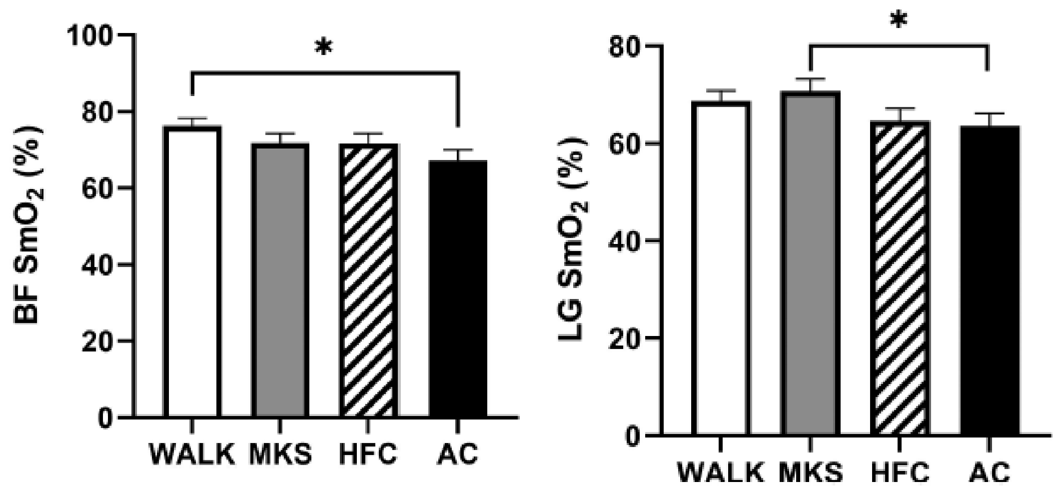

Figure 3 Muscle Oxygen saturation in the biceps femoris (BF) and in the lateral gastrocnemiuls (LG) muscle for normal walking (walk), knee scooters (MKS), hands-free crutch (HFC) and axillary crutches (AC).

Decreased Muscle Atrophy

A large body of scientific evidence suggest that crutches lead to muscle atrophy and strength losses after a period of non-weight bearing. The knee flexion angle has a significant impact on muscle atrophy according to prior 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 mitigate strength losses. This conclusion is further supported based on prior studies that showed an increase in muscle activity, blood flow as well as muscle oxygen saturation with the HFC when compared to both crutches and knee scooters in the non-weight bearing limb. This result provides evidence that the HFC can mitigate muscle atrophy and strength losses in specific muscle groups over a period of non-weight bearing which would address an unmet need for an ambulation device that can mitigate muscle atrophy. *See Appendix A.6 for details and citations*

Improves Stability and Safety

A mobility device that improves stability is key to prevent falls and secondary injuries. Research shows that the HFC leads to a significantly lower whole-body angular momentum as compared to crutches which proves that HFC users have a lower risk of falling and overall better balance control during ambulation over crutches. A greater range of whole-body angular momentum has been associated with an increased risk of falling and poor balance due to the larger gait margin of stability and wider step width during gait. The mean range of whole-body angular momentum from this study can be seen in Figure 4 for six device conditions of NONE – no crutch or walking boot, BOOT – walking boot only, HFC – HFC only, HFCBOOT – HFC with a walking boot, SAC – crutch only, SACBOOT – crutches with a walking boot.

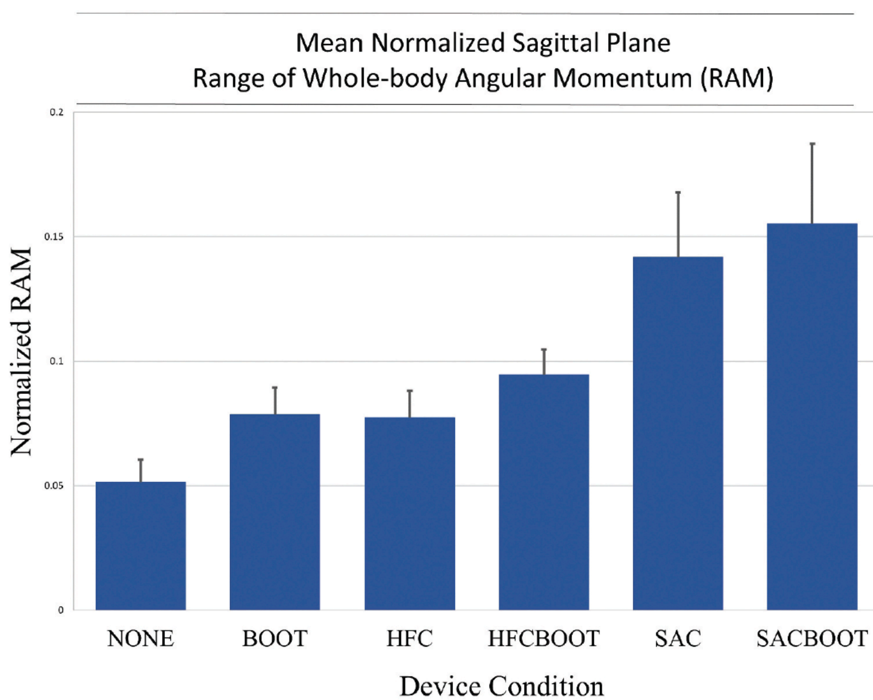

Figure 4 Mean range of whole-body angular momentum over a gait cycle for six conditions.

Due to the reciprocal limb motion while ambulating with the HFC, the whole-body angular momentum with the HFC was found to follow a sinusoidal pattern that is most similar to ambulating without an assistive device with positive peaks, while crutches lead to a large peak in angular momentum as a result of the swing-through gait of both limbs within a gait cycle (Figure 5).

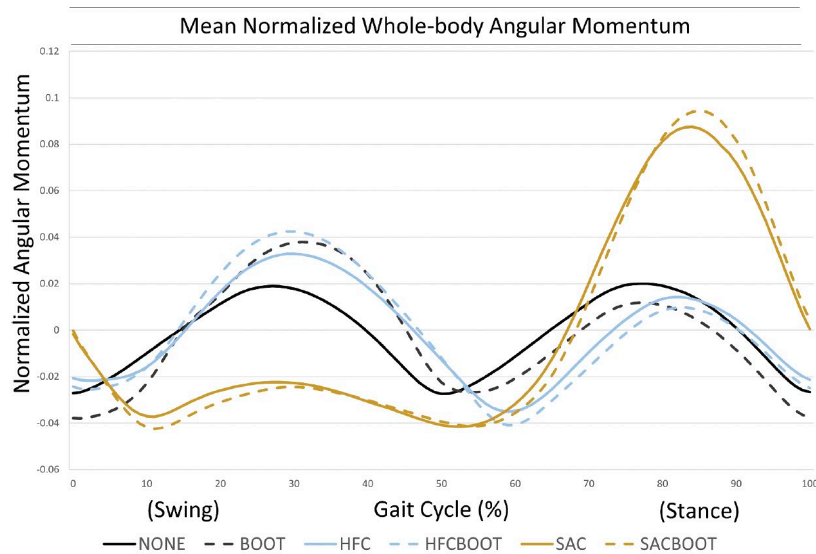

Figure 5 Average normalized sagittal plane whole-body angular momentum for all participants from heel strike to heel strike.

The result of this study is significant as it directly relates to user safety, and shows that HFC users are able to better control angular momentum while ambulating making HFC users less susceptible to falls compared to crutch users. *See Appendix A.7 for details and citations*

Faster Recovery, Reduced Healthcare Costs and Faster Returns to Work

Muscle activity, blood flow, muscle oxygen delivery, muscle atrophy and safety have a direct impact on healing and the recovery time for lower limb injuries. Prior research that shows that the HFC provides improved muscle recruitment, less atrophy, increased blood flow as well as improved oxygen delivery to the affected limb will result in accelerated and enhanced healing for patients with lower limb injuries. Research demonstrated that HFC users were less susceptible to falls compared with crutches which has a direct impact on patient safety and recovery mitigating further complications and secondary injuries that are widely known with crutch use. Another independent study analyzed knee scooters, revealing high fall rates and associated injuries. A randomized clinical trial using patients that were using the HFC showed that they were discharged faster than patients who did not use it. *See Appendix A.8 for details and citations*

Ability to Perform Day to Day Activities (ADLs)

Because the HFC does not require upper-extremity usage similar to crutches and knee scooters in order to ambulate, routine daily activities that a person would perform with weight bearing restrictions are either impractical or not possible using crutches and knee scooters while such activities are entirely possible using the HFC. Research shows that the HFC is superior over both crutches and knee scooters to perform activities of daily living. Subjects found completing activities of daily living easier with a HFC compared to both crutches and knee scooters (Figure 6). Preference and ease of use for the HFC has a direct impact on better patient compliance to non-weight bearing recommendations. Lack of compliance can not only lead to further injuries and complications, but also increase the costs on the healthcare system in the treatment of such injuries. *See Appendix A.9 for details and citations*.

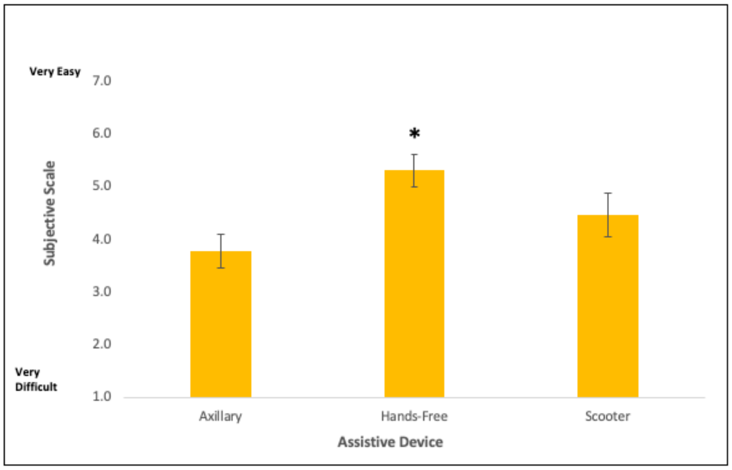

Figure 6 Ease of performing activities of daily living for different mobility devices

Elimination of Secondary Injuries Related to Mobility Device Use and Stability

Crutches often lead to secondary injuries such as Carpal Tunnel, axillary nerve damage, crutch palsy 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. The HFC has an impeccable safety record with zero reported injuries since its introduction in 2001. Direct published research also shows that subjects using the HFC did not experience any falls during the testing periods. Another study comparing the stability of HFC users to crutch users showed that the HFC led to a significantly lower range of angular momentum thereby proving that HFC users are able to better control balance during ambulation, are less susceptible to falls and fall related secondary injuries when compared to crutch users. The lack of the reciprocal motion of the arms and legs with crutches may have contributed to the significantly greater range of angular momentum for crutch users. The HFC was found to exhibit an angular momentum pattern that resembles normal unassisted walking. Like crutches, knee scooters are another commonly used ambulation device that requires the use of hands in order to ambulate during the recovery of a lower limb injury. Prior published research report that knee scooter users have a high rate of falling with a large prevalence of scooter related injuries and as a result of this knee scooter users are susceptible to further complications and subsequently in the delay of full recovery. *See Appendix A.10 for details and citations*

Increased Patient Compliance

Because activities of daily living are difficult or impossible to do with both knee scooters and crutches due to the use of both hands during ambulation, non-compliance to non-weight bearing instructions are common and often cause re-injuries that extend the recovery time and lead to further complications as was reported in prior studies for crutch and knee scooter users. Moreover, knee scooters can be limiting in environments that require ascending or descending stairs or navigating in limited spaces. The HFC offers hands free mobility and independence with the added benefit of allowing stair climbing and easy navigation in small areas and reciprocal motion similar to normal unassisted walking. When all other benefits of using the HFC are coupled, this ultimately enables the ability to perform daily activities which in turn has a direct impact on increasing patient compliance to non-weight bearing instructions. Prior research directly showed that the HFC is preferred over both crutches and knee scooters when performing activities of daily living and that the knee scooter has clear limitations on stairs and rough terrain. *See Appendix A.11 for details and citations*

Less Fatigue

While crutches are the most common ambulation device used for lower limb injuries, a large body of scientific research shows that crutches lead to higher energy expenditure when compared to normal unassisted walking which have been known to contribute to poor compliance to remain non-weight bearing and as a result of this leading to further injuries and complications. Furthermore, crutch users were shown to experience greater pain compared to the HFC according to a published study in the Journal of Foot and Ankle Orthopaedics. Patients experienced less discomfort and fatigue using the HFC. A direct study that measured aerobic energy expenditure and substrate utilization for traditional walking and ambulation using the HFC, knee scooter and crutches showed that the substrate utilization with the HFC was not significantly different than normal walking. Exertion and pain scores were lower in HFC compared to crutches. One study in particular directly measured the oxygen consumption while using the HFC, knee scooter and crutches to link this outcome measure to energy expenditure. The results of that study showed that the HFC is the only mobility device that led to lower energy expenditure when compared to axillary crutches (Figure 7a) while also allowing stair climbing and activities of daily living when compared to crutches and knee scooters (Figure 7b). *See Appendix A.12 for details and citations*

(a) (b)

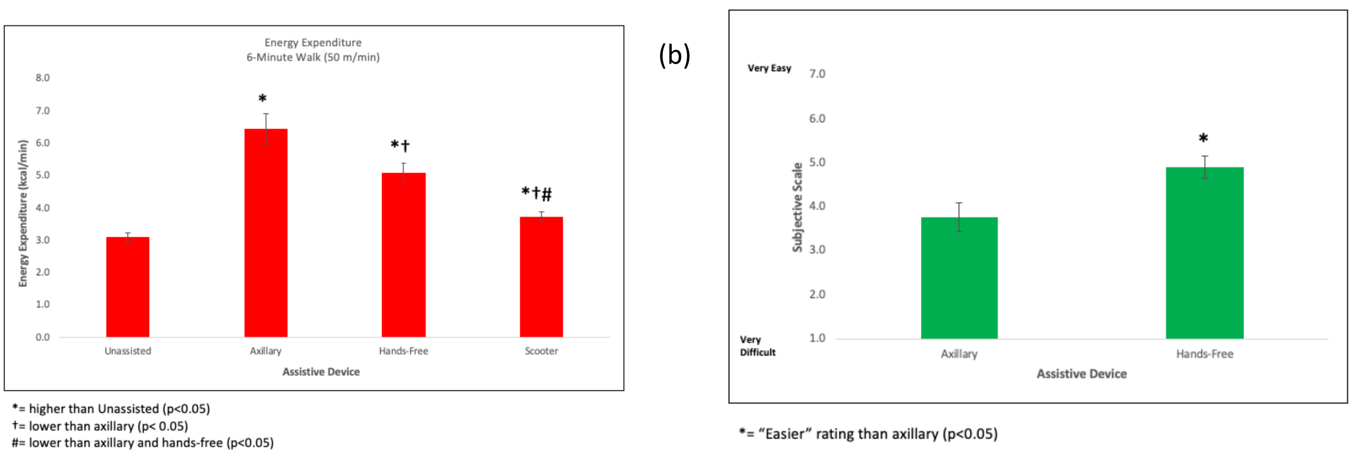

Figure 7 (a) Energy Expenditure 6-minute walk at 50m/min and (b) ease of climbing a flight of stairs

Decreases in Changes of Human Brain Plasticity

Structural plastic changes in gray matter and white matter have been observed after a period of immobilization. Because such plastic changes impact motor movements, it is important to consider the impact mobility devices have on cortical thickness and fractional anisotropy. The HFC leads to significantly greater muscle activity in the rectus femoris, vastus lateralis, gluteus maximus and lateral gastrocnemius when compared to crutches and knee scooters thus is expected to minimize the effect of non-weight bearing recommendations on human brain plasticity. *See Appendix A.13 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). This finding is consistent with other prior literature which report participants preffering the HFC over crutches (Wiederien et al., 2023). Patient satisfaction, safety and preference can be a major determinant for compliance to non-weight bearing recommendations (Bateni & Maki, 2005; Faruqui & Jaeblon, 2010; 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). Prior research shows that subjects prefer the HFC over both crutches and knee scooters in completing activities of daily life while knee scooters presented a clear limitation in environments that contain stairs or rough terrain (Canter et al., 2023). This study further argued that the preference for the HFC compared to the knee scooter was a result of subjects being unable to climb stairs or complete the stair portion of the ADL course as it was too difficult to carry the scooter over the steps in this course. One other reason why the HFC is favorable among subjects compared to crutches may be explained by the lower exertion, heart rate, energy expenditure and pain scores when using the HFC as shown in various published studies (Canter et al., 2023; Hackney et al., 2022; Martin et al., 2019).

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 et al., 2021; Dewar & Martin, 2020). 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 as was shown in various prior studies (Clark et al., 2004; Dewar et al., 2021; 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 has a direct impact on decreasing muscle atrophy, increasing blood flow, reducing the risk of deep vein thrombosis (DVT) and enhancing healing (Bradley et al., 2022; Broderick et al., 2009; Dewar et al., 2021; Dewar & Martin, 2020; Faghri et al., 1997; Rasouli & Reed, 2020; Vinay et al., 2021). Each of these benefits of the heightened muscle activation using the HFC are supported with direct and associated studies in the following sections.

A.3 Blood Flow

A study published in Foot and Ankle Orthopaedics compared the blood flow and vessel dimensions following ambulation using the HFC, knee scooter and crutches for 40 participants (Bradley et al., 2022). This study found that the HFC led to a significantly lower decline in blood flow when compared to both knee scooters and crutches in popliteal blood flow and vessel dimension (Bradley et al., 2022). The results of this study corroborate the findings of other prior works which reported a significant decline in blood flow for knee scooters (Ciufo et al., 2019) with crutches leading to the greatest decrease (Reb et al., 2021). The elevation in blood flow with the HFC can be attributed to the heightened muscle activity with the HFC in the suspended limb compared to both crutches and knee scooters (Bradley et al., 2022; Dewar et al., 2021; Dewar & Martin, 2020). This study along with other research have shown that muscle activity has a major impact on blood flow (Bradley et al., 2022; Bradley & Hernandez, 2011; Reb et al., 2021). Reductions in blood flow is a major concern during a period of immobilization. Research shows that blood flow can be reduced by 61% after 8 hours of constant sitting (Kurosawa et al., 2022). When poor blood flow continues as a consequence of prolonged immobilization, it can present as deep vein thrombosis (DVT) in the lower extremities (Broderick et al., 2009; Faghri et al., 1997; McLachlin et al., 1960; Vinay et al., 2021) and cause pain, venous congestion and life-threatening pulmonary embolisms (PE) (Bradley et al., 2022). In particular, blood pooling of more than 48 hours was associated with developing a DVT in one prior study (Tesch et al., 2004). Reduced blood flow can also impact oxygen delivery to the injured muscle and bone which is important for healing (Lu et al., 2013; Rodriguez et al., 2008). In particular, one study found that muscle oxygen saturation to the muscles of the lower extremity was reduced with crutches as a result of the lower blood flow for crutches (Bradley et al., 2023) as was also argued in a previous study that measured blood flow for crutches, knee scooter and the HFC (Bradley et al., 2022). On the other hand, the HFC in both studies far exceeded crutches in blood flow and oxygen delivery with levels similar to normal unassisted walking (Bradley et al., 2022; Bradley et al., 2023). Popliteal venous blood flow of both crutches and knee scooters were impaired (Bradley et al., 2022). A fixed knee angle has been believed to have a direct impact on increasing the risk of developing a deep vein thrombosis in some prior studies (Bleeker et al., 2004; Ciufo et al., 2019). In particular, one study found that the flexed knee position during knee scooter use led to a significant reduction in blood flow (Ciufo et al., 2019). However, these aforementioned negative effects of knee flexion angle can be negated with the HFC due to the increased muscle activity in the suspended limb (Bradley et al., 2022; Dewar et al., 2021; Dewar & Martin, 2020). Moreover, these studies demonstrated that muscle activity in the suspended limb has a greater impact on blood flow than the knee flexion angle (Bradley et al., 2022; Dewar et al., 2021; Dewar & Martin, 2020) which is in agreement with another study arguing a similar conclusion (Reb et al., 2021) thereby changing the notion that knee flexion angle alone leads to developing a deep vein thrombosis.

A.4 DVT Risk Reduction

It is generally understood that the incidence of developing a deep vein thrombosis (DVT) is higher for patients with lower limb non-weight bearing injuries than for the general population (Saragas et al., 2014; Sullivan et al., 2019). For instance, the prevalence of DVT for patients after a foot and ankle surgery were reported to be as high as 32% (Saragas et al., 2014). The risk of DVT is a direct consequence of immobilization for prolonged periods of time due to the reduction in blood flow (Bleeker et al., 2004; Bradley et al., 2022; Ciufo et al., 2019), muscle pump activity (Dewar et al., 2021; Dewar & Martin, 2020) and muscle oxygen delivery (Bradley et al., 2023) for both knee scooters and crutches when compared to normal unassisted walking. Such prior studies support research that have directly shown blood pooling in the lower extremity as a consequence of crutch usage with an increase in calf circumference after a prolonged period of time (Tesch et al., 2004). A published study comparing the blood flow and vessel dimensions after using the HFC, knee scooter and crutches found that unlike knee scooters and crutches, the HFC did not lead to statistically significant reductions in popliteal blood flow and vessel dimension when compared to unassisted normal walking (Bradley et al., 2022). In addition to this, the HFC leads to a heightened level of muscle activity in the injured limb explaining the increased blood flow observed using the HFC due to prior studies that have shown the influence muscle activity has on blood flow (Bradley & Hernandez, 2011; Dewar et al., 2021; Dewar & Martin, 2020; Reb et al., 2021). Furthermore, crutches have been shown to elevate deoxygenated hemoglobin in the vastus lateralis, biceps femoris and lateral gastrocnemius muscles beyond levels typically measured for unassisted walking (Bradley et al., 2023). An increase of deoxygenated hemoglobin has been associated with the risk of developing a DVT in prior studies (Yamaki et al., 2011). This result is impactful as it has been argued in prior research that a flexed knee angle leads to increasing the risk of DVTs (Ciufo et al., 2019; Reb et al., 2021). For instance, subjects who sat for a prolonged period of time were shown to be more likely to develop a DVT according to one study (Kurosawa et al., 2022). Use of knee scooters, like sitting, fixes the knee angle to be approximately 90 degrees for a prolonged period of time. Another prior study argued that knee scooter users are more susceptible to developing a DVT due to the knee flexion (Ciufo et al., 2019). Furthermore, this study concluded that knee flexion had a direct impact on blood flow due to the reduction in blood flow observed using a knee scooter (Ciufo et al., 2019). However, these studies were limited in that it did not consider the decrease in muscle activity when both sitting as well as ambulating using the knee scooter as muscle pump activity is crucial for preventing stasis (Reb et al., 2021). Like scooters, the HFC has a knee flexion angle that is approximately 90 degrees. However, unlike knee scooters and crutches, the HFC does not lead to a statistically significant reduction in blood flow and muscle activity (Bradley et al., 2022; Dewar et al., 2021; Dewar & Martin, 2020). This result shows that the negative effects of knee flexion can be mitigated with the HFC and that muscle activity has a greater impact on blood flow and reducing the risk of DVT than knee flexion.

A.5 Muscle Oxygen Delivery

It is widely accepted that wound and bone healing as well as basic cellular processes rely on muscle oxygen delivery to the injured site (Lu et al., 2013; Rodriguez et al., 2008; Sen, 2009). For instance, the aerobic metabolism responsible of generating adenosine triphosphate (ATP) in the mitochondria require oxygen (Ferretti et al., 2022; Sen, 2009) as well as various enyzmes that play a vital role in healing (Zhang et al., 2002). Impairment in bone repair are also observed when there is a lack of cyclooxygenase-2 activity (Zhang et al., 2002). Finally, if there is a reduction in tissue oxygen, this may impact collagen synthesis (Fong, 2009). Improving oxygen delivery to the injured limb has also implications in reducing muscle atrophy and the risk of developing a deep vein thrombosis which is a common issue with immobilization (Bradley et al., 2023; Sullivan et al., 2019; Yamaki et al., 2011). A direct study measured muscle oxygen saturation during ambulatory walking and while using crutches, knee scooter and the HFC using a relatively large sample size of 38 participants (Bradley et al., 2023). Infrared spectroscopy sensors were placed on the vastus lateralis, biceps femoris, and lateral gastrocnemius muscles of the non-weight bearing limb. This study found that there were no significant changes in muscle oxygen saturation with the HFC when compared to unassisted walking, while there were statistically significant declines in oxygen delivery for crutches in the bicep femoris and lateral gastrocnemius muscles (Bradley et al., 2023).

A.6 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 (Altinkaynak, 2022; Bradley et al., 2022; Dewar et al., 2021; Dewar & Martin, 2020). Prior research shows that the degree a muscle will atrophy is dependent on the activity of the muscle (Clark, 2009; MacLennan et al., 2020; Magill et al., 2019; Sanders et al., 2018). Moreover, the increase in muscle oxygen saturation to the muscles of the non-weight bearing limb while using the HFC can also reduce muscle atrophy after a period of non-weight bearing (Bradley et al., 2023). 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 (Magill 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° (Altinkaynak, 2022). 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., 2008; Hather et al., 1992; Tesch et al., 2016).

A.7 Stability

Dr. Jason Wilken, a recognized expert in walking stability and falls in the Department of Physical Therapy and Rehabilitation Science at the University of Iowa conducted a research study that directly compared the walking stability of both the HFC and crutches using the range of angular momentum as the outcome measure for both mobility devices with or without a walking boot (Wiederien et al., 2023). This study found that HFC users had a significantly lower range of whole-body angular momentum compared to crutch users in both conditions (Wiederien et al., 2023). The range of whole-angular momentum is crucial for balance control during human locomotion (Herr & Popovic, 2008). In particular, a larger range of whole-body angular momentum in the sagittal plane has been shown to be associated with an increased risk of falling and poor balance during gait in several prior studies (Bennett et al., 2010; Herr & Popovic, 2008; Nolasco et al., 2019; Nott et al., 2014; Pickle et al., 2017; Pickle et al., 2014; Robert et al., 2009; Sheehan et al., 2015; Silverman & Neptune, 2011; Silverman et al., 2014; Vistamehr et al., 2016). Based on such prior research that provides the direct impact angular momentum has on walking stability coupled with the study that has shown that the angular momentum is significantly greater using crutches compared to the HFC, this proved that patients are at more risk of falling when using crutches than the HFC (Wiederien et al., 2023) which has been reported as a common concern with mobility device use (Hefflin et al., 2004). For instance, falling is known to be a common concern for knee scooters in literature (Rahman et al., 2020). Because the HFC recruits both legs and arms during locomotion similar to normal unassisted gait, this study also found that the HFC leads to an angular momentum pattern closest to normal unassisted gait that is sinusoidal with positive peaks corresponding to the rapid advancement of the swing limb of each limb (Wiederien et al., 2023). In contrast, crutches were shown to have a negative angular momentum the first half of the gait cycle and subsequently a large positive peak in the last half of the gait cycle as both limbs advance simultaneously (Wiederien et al., 2023). Such a significant difference in angular momentum patterns is associated with an increased risk of falling (Vistamehr et al., 2016). This result corroborates other prior studies which showed that patients feel safer using the HFC (Rambani et al., 2007) and prefer the HFC over crutches (Canter et al., 2023; Martin et al., 2019). The result of this study is impactful as it relates to the overall safety of mobility device choices, and can guide medical providers during the prescription of an assistive device for patients who require to remain non-weight bearing due to a lower limb injury.

A.8 Recovery Time

A randomized control trial conducted using 80 patients showed that patients were discharged significantly faster after using a HFC compared with not using the HFC (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 developing a deep vein thrombosis and pulmonary embolism (Bradley et al., 2022; Dewar et al., 2021; Dewar & Martin, 2020). The increased muscle oxygenation saturation using the HFC via improved blood flow also enhances healing (Bradley et al., 2023; 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, the HFC leads to faster therapeutic gains. Moreover, secondary injuries as a result of using crutches or knee scooters falling (Rahman et al., 2020; Yeoh et al., 2017) are nonexistent when using a HFC in addition to the better stability compared to crutches which all contribute to reducing the recovery times of lower limb injuries (Wiederien et al., 2023)

A.9 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, stairs, etc. are possible with the HFC (Canter et al., 2023). 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 is preferred over both crutches and knee scooters (Canter et al., 2023; Martin et al., 2019; Wiederien et al., 2023). Researchers Dr. Timmerman and Dr. Reidy at the Department of Kinesiology and Health of Miami University conducted a direct study that aimed to investigate the ability to perform activities of daily living (ADLs) using a HFC compared to crutches and knee scooters (Canter et al., 2023). This study found that subjects preferred the HFC over both crutches and knee scooters during ambulation, stair climbing and activities of daily living while the knee scooter led to a clear disadvantage for stair climbing and on rough terrain (Canter et al., 2023). Furthermore, subjects found the HFC easier to use than crutches and knee scooters and had a lower heart rate, perceived exertion and energy expenditure (Canter et al., 2023).

A.10 Secondary Injuries

Although crutches are the most prescribed assistive device (Kaye et al., 2000; Martin et al., 2019; Rambani et al., 2007), prolonged use of crutches have been shown to lead to various secondary injuries (Dalton et al., 2002; Manocha et al., 2021). 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 (McFall et al., 2004; 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). Because there is no loading of the hands and upper extremity when using a HFC, secondary injuries have not been reported with the HFC. Secondary injuries also occur with knee scooters due to the increased risk of falling (Rahman et al., 2020; Yeoh et al., 2017). The HFC leads to better stability and a lower risk of falling compared to crutches (Wiederien et al., 2023). Due to this, HFC users are less susceptible to fall related injuries increasing the safety of mobility device users.

A.11 Patient Compliance

The HFC improves patient compliance to non-weight bearing restrictions, due to prior research that shows that patients with lower limb injuries prefer a HFC over crutches and the important role patient preference plays on patient compliance (Canter et al., 2023; Martin et al., 2019; Wiederien et al., 2023). In addition, because patients are able to function independently using the HFC with the ability to do activities of daily living (Canter et al., 2023; Rambani et al., 2007), the HFC will lead to better compliance. Published research shows that patients prefer the HFC over crutches and knee scooters when completing activities of daily living (Canter et al., 2023; Martin et al., 2019; Wiederien et al., 2023). Patients with lower extremity injuries have been known to be noncompliant with prescribed weight bearing restrictions while using crutches likely due to the pain, discomfort and limitations of performing activities of daily living (Chiodo et al., 2016; Gershkovich et al., 2016; Kubiak et al., 2013; Martin et al., 2019). However, lack of compliance can lead to secondary injuries and further complications such as wound breakdown, loss of fracture fixation or hardware failure (Gershkovich et al., 2016).

A.12 Energy Expenditure

There is a large body of research that have shown that crutches are attributed to significantly higher energy costs compared to normal unassisted ambulation (Dounis et al., 1980; Holder et al., 1993; Mcbeath et al., 1974; Nielsen et al., 1990; Sankarankutty et al., 1979; Thys et al., 1996). Increased physiological demand has been shown to be an important factor in discontinuance and noncompliance to weight bearing restrictions with crutch use (Bateni & Maki, 2005). Therefore, mobility devices designed to assist ambulation should keep energy expenditure to a minimum while still allowing normal walking speeds and the ability to do their activities of daily living. A study published in the journal of Foot and Ankle Orthopaedics compared the metabolic cost of ambulation using a portable metabolic analyzer for subjects using a HFC, crutches and knee scooter. This study found that the HFC led to substrate utilization most similar to normal unassisted gait with the least amount of aerobic energy while allowing one to use both hands for activities pertaining to daily life (Hackney et al., 2022). Similar to this study, another study was designed to measure the energy expenditure with a portable indirect calorimetry system for the HFC, knee scooter and crutches this time while completing activities that simulate tasks one would complete in daily life. The results of this study suggested that the HFC was the only mobility device that resulted in energy expenditure similar to normal walking while also allowing users to complete all tasks within the validated ADL course (Canter et al., 2023). Immediately after completing the ADL course subjects were asked how difficult they found ambulating with each assistive device using a Likert scale. The results of this data showed that subjects found using the HFC significantly easier than crutches which correlates with the lower energy expenditure measured using the HFC (Hackney et al., 2022) as well as the lower exertion and heart rate reported for HFC users in other prior studies (Bhambani & Clarkson, 1989; Canter et al., 2023; Hackney et al., 2022; Martin et al., 2019).

A.13 Brain Plasticity

It is well accepted that limb immobilization effects human brain plasticity (Langer et al., 2012). In particular, it was shown that the cortical thickness (gray matter) of the sensorimotor cortex and fractional anisotropy (white matter) decreased after a period of immobilization which are both responsible for processing somatosensory information and impact motor movement (Langer et al., 2012). Because the HFC is the only mobility device that leads to muscle activity in the non-weight bearing limb consistent with normal walking when compared to crutches and knee scooters (Dewar et al., 2021; Dewar & Martin, 2020), the reorganization of the sensorimotor system as well as the overall effect of remaining non-weight bearing for prolonged periods on human brain plasticity is minimized with the HFC when compared to crutches and knee scooters.

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