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PRELIMINARY ANALYSIS OF THE

RE-FLEX (Vertical Shock Pylon)

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INTRODUCTION

For optimum gait efficiency it is imperative that prosthetic devices keep energy expenditure to a minimum. Prosthetic feet are a highly important multifaceted component of the prosthesis, with its primary purpose to serve in place of the anatomical foot and ankle. Amputation results in an increased metabolic energy consumption (Ec) during ambulation (Waters et al. 1976; Gonzalez et al. 1974). The increase in Ec can be partially attributed to the loss of musculature and the ankle joint, in below knee (Bk) amputees.

During ambulation, Energy Storing Prosthetic Feet (ESPF) have reported to provide no significant alteration to an individuals metabolic energy expenditure at lower walking speeds. It has been demonstrated that as walking velocity increases, ESPF improve gait characteristics and reduce Ec (Thielsen et al. 1988). However, Torburn et al. (1990) and Lehmann et al. (1993) obtained different results. Lehmann and Torburn found no difference in Ec whilst wearing ESPF or 'standard' prosthetic feet at low or high walking velocities.

Energy cost of a prosthetic foot may be examined by having subjects walk at a selected speed and monitor the oxygen consumption of the individual, as an indicator of their energy used at differing walking speeds. Additionally, recording the self-determined speed at which an amputee will walk indicates the amount of energy required to ambulate with that componentry. This is known as an individuals Self-selected walking velocity and has been observed to be the most
efficient method of measuring energy expenditure (Corlett and Mahadeva 1970; Salvendy and Pilitsis 1971; Gonzalez et al 1974). Amputees, will therefore choose a walking velocity which minimises their energy demands. Subsequently, the foot which provides the highest self-selected walking velocity will prove itself to be the most energy efficient.

Amputation and the loss of shock absorption provided by removed tissues may result in detrimental effects for the amputee. Effective shock absorption is necessary to avoid proximal joint disease in lower limb amputees (Van Leewan 1980).

The ideal prostheses should not transmit shocks higher than those experienced in a normal lower leg. Wirta (1991) concluded that "...subjects preferred devices which developed the least shock and greatest damping", whilst Ehara (1993) found that amputees do not prefer a foot that releases large amounts of energy and preferred feet that absorbed a large amount of energy.

Flex Foot Inc. have developed and produce a piece of prosthetic componentry named the Re-Flex (VSP) (Figure 1).

![Figure 1: The Re-Flex (VSP)](image)
The Re-Flex is a Foot and Shank set-up which incorporates a modified Flex Foot and Vertical Shock Pylon (VSP), which is designed to provide vertical shock absorption through its telescoping tube and carbon fibre side spring. The VSP together with the Flex Foot is claimed by its manufacturer to provide a comfort level and shock absorption far superior to all other prostheses.

The purpose of this study was to investigate the influence the Re-Flex componentry has upon metabolic energy expenditure compared to a conventional (SACH foot and Aluminium shank) set up at differing walking velocities. The amount of shock absorption provided by the Re-Flex will be determined and examination of the influence the VSP has alone will be investigated.

These parameters were chosen because they are excellent indicators of amputee performance, and due to the complete absence of literature which objectively evaluates this componentry. Results found will be able to assist as a guideline for prescription.
METHODOLOGY

Design

Three separate tests were conducted. Tests A and B were conducted simultaneously, whilst Test C was performed at another time. Each test was conducted three times to examine the three different conditions, testing different componentry within each condition. The initial condition was the Re-Flex (VSP) (Figure 2). The second condition was the Re-Flex with the VSP component immobilised (Figure 3), and the third condition consisted of testing conventional componentry (Figure 4).

Test A examined the energy expenditure of each condition, whilst Test B recorded the shock absorbing capacity of each condition, concurrently. Test C investigated the self-selected walking velocity the subject adopted under each condition.

Subject

For this investigation only one subject was examined due to limited subject availability, as selection criteria required that the subject possess their own Re-Flex prosthesis with the capacity for the replacement of the Re-Flex component with the conventional componentry.

The subject of this study was a highly active 23 year old male who weighed 82 kilograms. He was a traumatic Trans-tibial (tibial) amputee with a residuum length of 150mm and was a highly
proficient walker and runner.

Procedure

Three sessions, on separate days, were required to complete subject testing. Initially, the subject was supplied with his conventional componentry, which was fitted and optimally aligned to his already existing socket. The subject was fitted and acclimatised to this different prosthetic componentry for a minimum of 24 hours prior to testing commencement.

The second session consisted of the testing, which was performed in one four hour session, due to patient time restraints. The subject was tested at graded walking speeds on a treadmill, in a randomised order, according to the condition and walking velocity being examined. Standardisation of walking speeds through the use of a treadmill was necessary to facilitate and record comparable measurements. Walking velocities examined were 2.8, 3.8 and 4.8 kilometres per hour. Componentry was removed and replaced after each trial, with a single socket used for the duration of the investigation.

Habituation to treadmill walking at different velocities was addressed by allowing the subject to acclimatised to treadmill walking and achieve a steady state, in accordance with Wall and Chateris (1980) findings. This was achieved by providing a twenty minute walking period of alternating velocities prior to testing commencement.

Oxygen consumption is an indicator of Ec, and therefore
gait and prosthetic efficiency was measured with an Oxylog. Shock absorption was measured with an accelerometer. The accelerometer was mounted, externally on the side of the prosthesis socket.

The third session was the determination of self-selected walking velocity through the use of time trials. A four hundred meter track was used with a one lap acclimatisation period followed by a one lap time trial for each of the conditions.
RESULTS

Oxygen Consumption During Walking

The comparison of Ec, through the uptake of oxygen, at walking speeds of 2.8, 3.8 and 4.8 km/hr are illustrated in Figure 5.

At 2.8 km/hr there was no difference in O2 use between any of the test conditions.

An increase in O2 use was seen at the walking velocity of 3.8 km/hr. In all conditions a proportional increase was evident with no foot showing a significant advantage over another.

At the 4.8 km/hr walking velocity, again, there was an increase in Ec, which is expected due to the increased workload. The SACH Foot had the highest O2 consumption level. The Reflex without the VSP had a 9% decrease in O2 consumption, with the Reflex (VSP) being the most energy efficient foot tested. 17% less oxygen was used with the Re-Flex than with the SACH and 8% less than with the Re-Flex without VSP.

Under each of the test conditions investigated, there was negligible, if any, difference between the Ec at 2.8 and 3.8 km/hr. The 4.8 km/hr walking velocity demonstrated a considerable difference between the three separate conditions.
### Nett Oxygen Consumption

![Bar chart showing Nett Oxygen Consumption for different velocities: SACII, RE-FLEX, and VSP-OUT.

<table>
<thead>
<tr>
<th>Walking Velocity</th>
<th>SACII</th>
<th>RE-FLEX</th>
<th>VSP-OUT</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0KPH/HR</td>
<td>0.55</td>
<td>0.65</td>
<td>0.65</td>
</tr>
<tr>
<td>3.0KPH/HR</td>
<td>0.75</td>
<td>0.7</td>
<td>0.62</td>
</tr>
<tr>
<td>4.0KPH/HR</td>
<td>1.12</td>
<td>0.93</td>
<td>1.02</td>
</tr>
</tbody>
</table>

**Figure 5**
Self-Selected Walking Velocity

Each condition tested resulted in a different self-selected velocity. Figure 6 demonstrates these findings, with the Re-Flex condition providing the fastest walking velocity, recording 1.61 metres per second (m/s). The SACH foot and the VSP immobilised provided minimal difference between their velocities, being 1.56 and 1.57 m/s respectively.
Shock Absorption at Heel Strike

The transmission of shock through each of the prosthetic foot to the socket was examined, with the results of this direct comparison shown in Figure 7.

At the walking velocity of 2.8 km/hr the ReFlex was shown to provide the greatest absorption of shock, followed by the SACH foot. The Re-Flex, without the VSP, demonstrated that it was the least effective in providing shock absorption at this walking speed.

Similar values were found at 3.8 km/hr, as those seen at 2.8 km/hr. All recordings were larger with the SACH and ReFlex rising similarly, but the ReFlex, without the VSP, increased negligibly. The Re-Flex demonstrated the highest level of shock absorption with the immobilised VSP Re-Flex providing the least.

The walking velocity of 4.8 km/hr demonstrated that the ReFlex, once again provided the greatest protection against shock transmission from the foot to the socket. At this increased velocity the ReFlex, with the immobilised VSP, provided greater protection from shock than did the SACH.

Both the SACH and ReFlex showed greater values of shock transmission at increasing walking velocities. The ReFlex, with the VSP immobilised, showed almost identical shock values at 2.8 and 3.8 km/hr, being 5.2g and 5.3g respectively. At 4.8 km/hr this foot showed a considerable decrease in shock transmission to the socket of 3.5 gravities, a 34% decrease in shock transmission.
Figure 7
DISCUSSION

Oxygen Consumption During Walking

A curvilinear increase in oxygen uptake occurs with increases in walking velocities (Nielsen et al., 1988) which was witnessed in this study.

Forbourn et al. (1990) found that "All foot-types resulted in oxygen consumption greater than normal." Additionally, Forbourn found that the type of prosthetic foot worn had no influence on energy expenditure. Gonzalez et al. supports these findings, in that he found optimal BK stump length causes a minimal rise in work load.

Barth et al. (1992) state "No significant differences were found in energy cost among the prosthetic feet tested..." whilst Lehmann et al. (1993) in comparing the Flex and Seattle feet to the SACH found there was no significant difference among the three feet designs relating to energy expenditure and there was no significant difference in the metabolic efficiency during running.

Colborne et al. (1992) in comparing a Seattle to a SACH foot found that the Seattle foot produced a small metabolic energy saving and suggested that the energy storing foot produced a more efficient gait, resulting in lower energy cost per meter walked.

Nielsen et al. (1988) states "...lower energy cost values observed at higher walking velocities for the Flex-foot ambulation compared to conventional foot walking." A 10% decrease in energy cost at 4 miles per hour (mph) was found by
Nielsen when comparing the Flex to the SACH foot and states that "...the energy storing-releasing design characteristics of the Flex-Foot were of negligible consequence at slow walking speeds, but at speeds equal to and above 2.5 mph walking performance was enhanced". These findings are supported by Bach and Wooley who conclude "...the Flex-foot resulted in substantial reduction of energy expenditure during running..."

The findings of this study at 2.8 and 3.8 km/hr in Test B demonstrate the lack of clinical difference between Nett oxygen consumption at 'normal' walking speeds, supporting the findings that there is no difference in energy consumption between prosthetic feet during normal walking.

Substantial differences were present in the 4.8 km/hr walking velocity, as a 17% reduction in energy expenditure with the Re-Flex Foot compared to the SACH was found. This recording supports findings reported by Nielsen et al. (1988) and Bach and Wooley (1986).

The Flex Foot component (VSP immobilised/ out) provided a decrease in Nett oxygen consumption compared to the SACH of 3%, at 4.8 km/hr. This evidence again supports findings that energy consumption is reduced at higher walking velocities with Re-Flex.

Additionally it is apparent that the VSP component of the Re-Flex was responsible for a further 8% reduction in energy consumption above that provided by the Flex Foot alone. The energy storage-return capacity of the leaf-spring of the VSP can therefore be seen to serve the function of reducing the
energy demands placed upon an amputee at higher than normal walking velocities.

Electromyographic (EMG) evidence investigating muscle activity during ambulation is required to demonstrate whether the leaf-spring has any influence upon muscle activation and amplitude patterns. It is anticipated that the Re-Flex would provide a more normal muscle activity reading, resulting in the reduced energy cost of this condition. Winter and Sienko (1988) found that the SACH foot produces abnormal hip and knee power output patterns, whilst Czerniecki et al (1991) discovered that Energy Storing Prosthetic Feet, especially the flex foot, reduced the magnitude of these abnormalities.
Self-Selected Walking Velocity

"Researchers have found that each amputee walks at a self-selected optimal, energy-efficient speed. By evaluating the amputee at self-selected walking for each foot, the energy cost for that foot can be determined." (Barth et al. 1992)

Barth et al. (1992) found, in their investigation of conventional and ESPF, that "...no significant changes in self-selected walking velocity occurred." Torburn et al. (1990) state "...the type of foot had no influence on energy expenditure at 15 minutes of free walking." Lehmann et al. (1993) additionally found that "The self-selected walking speed of the volunteers while wearing the three prosthetic foot designs was not significantly different."

Nielsen et al. (1988) conclude that "Ambulation with the Flex-Foot tended to facilitate faster walking approximating more normal values of self-selected walking velocity. ", compared to a conventional foot.

Findings of this study demonstrate that the Flex and SACH feet resulted in a negligible difference in their self-selected walking velocities. This result opposes findings found in test A, using the oxylog and treadmill and supports the findings of Lehmann et al (1993), Torburn et al and Barth et al, that prosthetic feet have no influence upon amputee self-selected walking velocity.

The Re-Flex foot was shown to have the highest self-selected walking velocity of the feet tested, providing a 5.5% advantage over the other feet investigated. This energy saving supports the treadmill/oxylog results that it provides
amputees with a reduction in energy consumption at higher than normal walking speeds.

The increase in walking velocity of 5.5% over the other foot appears to be attributable to the VSP component which provided an additional 8% energy saving over the VSP out/immobilised condition present in the treadmill conditions. This indicates that the VSP is a highly efficient energy-storing/energy-returning device that is more advantageous and applicable to amputee usage where energy expenditure is important.
Shock Absorption

The shock experienced at heel strike - known as the heel strike transient - was investigated. The Re-Flex was seen to provide the highest level of shock absorption in this study, supporting the claim made by its manufacturer that "...the Re-Flex VSP provides unprecedented shock absorption." (Flex Foot Inc.)

"Insufficient attenuation (of shock) by natural shock absorbers of locomotion systems causes overloading which may result in subchondral bone microfractures which would lead later to articular cartilage degeneration and osteoarthritis" (Wosk and Voloshin 1981). Rabin, et al 1978, found that the elimination of natural shock absorbing mechanisms in rabbits resulted in subchondral bone stiffening and metabolic changes of the articular cartilage, which leads to osteoarthritis.

At all walking velocities, the Re-Flex proved to be the most proficient shock absorptive device, followed by the SACH foot at 2.8 and 3.8 km/hr. At 2.8 km/hr the Re-Flex provided 11% and 72% more shock absorption than the SACH and VSP immobilised feet respectively. Whilst at 3.8 km/hr it provided a superior shock absorption level being 16% better than the SACH and 61% better than the VSP immobilised Flex foot.

The relatively good performance of the SACH foot at these walking velocities can be primarily attributed to the wedge heel cushion of the SACH. Wirta et al. (1991) examined the shock absorbing capacity of many prosthetic feet and found "The SACH demonstrated lower shock and higher damping values than in many other cases (of foot), yet many subjects rated
the foot as inferior." It was suggested that the SACH was not well suited for higher level activities such as running or dancing. Wirta et al. did not, unfortunately examine higher level activities such as running or dancing.

At 4.8 km/hr the SACH foot decreased its shock transmission by 2.0 gravities, or 41%, compared to its protection provided at 3.8 km/hr. At 4.8 km/hr the SACH proved to be 45% less effective than the Re-Flex. This dramatic increase in shock was not witnessed in either of the other conditions investigated and may indicate the presence of a threshold limit to the level that the heel cushion of the SACH foot provides adequate shock absorption.

This apparent threshold limit of the heel wedge supports the findings of Wirta et al. (1991) in the lack of subject preference for the SACH foot because of its inability to perform at higher activity levels.

The performance of the Re-Flex with the VSP immobilised demonstrated consistent shock recordings at 2.8 km/hr and 3.8 km/hr. At 4.8 km/hr this foot condition produced a decrease in shock from 5.3g at 3.8 km/hr to 3.5g, a 34% decrease in shock. This decrease represents an increased capacity for the modified Flex foot to provide an increased level of shock protection as the level of activity increases. The opposite of this was found with both the SACH and Re-Flex feet as they increased shock recordings as the walking velocity increased.

It is mere speculation to provide an explanation of the finding that the Flex foot/VSP immobilised provides increased shock absorption as walking velocity increases due to the
Limitations of the recordings taken within this study. Obviously further investigation must take place before conclusive causes can be proposed. Investigations performed by other researchers do suggest there are likely causes for these findings.

A possible cause for the increased efficiency of the Flex foot to provide greater shock absorption at higher walking velocities could include an alteration in muscle power output patterns. Winter and Sienko (1988) found the distribution of energy absorption at the lower extremity joints returned to normal with a Flex foot with the knee extensors the greatest energy absorbers followed by the ankle plantarflexors and hip extensors. Abnormally large eccentric hip extensor power output experienced with a SACH was reduced at the same time there was an increase in energy absorption of the knee.

Alternately, this increased walking velocity could cause a higher level of discomfort during walking at the stump-sOCKET interface. Amputees may therefore alter their gait patterns as discomfort increases, reducing impact upon the residuum.

Whilst these findings do provide evidence of altered muscle power output patterns with different feet, they do not mention the influence walking velocity has upon the characteristics of differing feet. EMG evidence is required to investigate the effect of walking velocity on muscles involved with walking, and how this differs with different feet.
CONCLUSION

The results of this study serve as an excellent pilot study, demonstrating the need for advanced and further research into the Re-Flex. Unfortunately, due to the limited (n=1) sample size this study has no reliability, statistical, or clinical significance. Another consideration is that as testing was performed on a young active amputee this study can only be applied to young active amputees.

As the purpose of this study was to investigate the performance of the Re-Flex foot componentry, compared to conventional componentry, it was found that:

1: The Re-Flex provided a substantial reduction in energy cost at the walking velocity of 4.8 km/hr compared to the SACH foot. The Vertical Shock Pylon component of the Re-Flex was responsible for a further 8% energy saving, above that provided by the Flex Foot component at this walking speed. None of the feet tested provided any benefit over another in reducing energy expenditure at the walking velocities of 2.8 and 3.8 km/hr.

2: The Re-Flex provided a more rapid self-selected walking velocity, being 5.5% faster than both other feet tested. By providing energy conservation at normal walking speeds and the faster completion of self-selected walking velocity trials demonstrates the effectiveness the Vertical Shock Pylon component of the Re-Flex in providing a reduction
in energy expenditure.

The Re-Flex was proven to provide the greatest level of shock absorption at all walking velocities, compared to the other componentry examined validating its manufacturers statements.

From this investigation it can be concluded that the Re-Flex provides a standard in prosthetic componentry which is superior to that of conventional componentry. It is recommended that a full scale investigation be performed to provide a reliable and significant study to substantiate, or correct the findings of this investigation.

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REFERENCES


