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Using Elevated Vacuum to Improve Functional Outcomes: A Case Report

--Manuscript Draft--

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Abstract:	ABSTRACT Elevated vacuum (EV) is a promising technology in the field of prosthetics. It has been shown to improve the fit of the limb in the socket, resulting in many possible benefits to the function of a prosthesis. However, very little research has been done on its effect on patient function. This unique case report was written to document the effect on one patient's function of transitioning from a patella-tendon-bearing (PTB) socket with ischial weight bearing thigh cuff (IWBTC) to prosthesis with an EV socket system. The patient underwent a transtibial amputation as a result of an avulsive trauma and used the PTB socket and thigh cuff for 16 years. In an effort to correct the patient's gait and improve his ability to perform the necessary tasks of his occupation, farming, the patient began using an EV prosthesis. He was interviewed and his functional status was evaluated one week, one month and one year after receiving the prosthesis. After one week the patient showed improvement in skin condition and expressed increased confidence in difficult locomotor tasks. At one month he was no longer experiencing pain in his sound side knee and his gait symmetry had improved dramatically. After one year the patient showed further improvement in gait and balance as well as the ability to wear the prosthesis comfortably for 24 hours at a time when necessary for his occupation. The transition from a PTB with IWBTC prosthesis to an EV system dramatically improved this patient's functional outcome and lessened the negative effects associated with wearing a prosthesis.
Response to Reviewers:	Dr. Boone, Here are my responses to the reviewers' suggestions. I actually have a color-coded copy of the manuscript where I have highlighted where I made a change. If it would be easier for you to see what changes I made using that copy, please let me know and I'll send it to you. Reviewer #1

	1.Not sure that the measures were necessarily the best ones to document the areas of interest proposed by the authors: functional status, pain, skin condition, locomotor tasks, gait symmetry, balance, and comfort. Other measures that could have been considered are visual analog scales for pain, the Prosthetic Evaluation Questionnaire (full or Mobility Subscale), the Orthotic and Prosthetic User Survey (functional status, quality of life and satisfaction with device and service), 6 Minute Walk Test (endurance), 10 Meter Walk Test (gait speed), Activities-Specific Balance Confidence Scale, Hanspal Socket Comfort Score, etc. The authors need to provide a clearer rationale for their choice of measures and why they believe they were the most appropriate for this case study. Answer: Since function is the single best predictor of patient outcome, it was chosen as the primary independent variable in this report. Pain, quality of life, satisfaction with device and service have all been shown to relate to function and were secondary parameters for this report, which is why I didn't choose the visual analog scales for pain, the full PEQ or the SCS. For the functional assessments, I was careful to select measures that were ecologically valid. For instance, the two spatiotemporal tests the reviewer mentions have limited capabilities to measure improvement over time, and it's not clear how valuable they really are to represent a person's mobility. Instead, I wanted a much more difficult and broader picture of the patient's abilities, especially because he is so active. Basically, he wanted to be able to comfortably perform difficult locomotor tasks, so I found the most difficult tests I could. I spent considerable time researching the tools available to measure function, and the AMPPro is currently recognized as the most valid, reliable and accurate tool. The LCI5 is actually part of the PEQ, and is actually better at measuring change than the full PEQ. As the reader says, I didn't provide clear rationale for the choice of measures, but I did revise the Assessment section, adding citations and justifying my decisions. 2.The value of the assessments is also limited by the lack of a baseline assessment of the original prosthesis. The authors claim that "that the EV prosthesis did in fact have positive effects" (page 8), but compared to what? All that the authors have documented is accommodation to the new prosthesis but not the benefits of this new prosthetic system compared to the old system. The only insight we gain in terms of comparison is through the non-standardized qualitative interviews rather than the validated assessments (LCI5 and AMPPro). The authors do not identify these and other limitations in the Discussion. Answer: I completely agree with this statement. Unfortunately, we didn't start taking data until the patient's first appointment with the EV prosthesis, so no quantitative baseline was obtained. I amended the Discussion as recommended. 3.The authors should provide a discussion of the limitations of their case study and how it affects the usefulness of the data. Answer: Thank you, I did this in the revised manuscript. 4.On page 5 the authors state that the subject's "limb displayed increased range of motion and muscle mass since he began using his PTB with IWBTC prosthesis" but how was this evaluated? This sentence refers to a single point in time evaluation and the case study supposedly focused on evaluations at time points after the transition to the EV prosthesis. Answer: I revised that spot on page 5 so that it is clearer. I was trying to justify why we made the switch to an EV prosthesis, since it was an unconventional move for a patient with knee instability. Most facilities would not have used EV with a patient with knee joint weakness because they would be concerned that removing the side bars would result in unsafe instability. We did it because we saw that he was getting stronger. 5. Again on page 5 the authors state, "In a gait evaluation, the patient demonstrated increased proprioception?increased anterior-posterior and medial-lateral stability?" How can a gait evaluation be used to assess proprioception? What does stability refer to? Later in the same paragraph, what does "based on the patient's increased stability?" mean?

Answer: The proprioception comment was my mistake. I amended that sentence and explained that the patient verbally expressed a feeling of stability, and the prosthetist confirmed it with visual inspection of the joint as he walked around the room.

6.On page 6, the authors should check that reference 8 refers to construct validity, not construction validity as there is no such thing to my knowledge.

Answer: Thank you, I fixed it.

7. Additionally, reference 8 refers to validity and reliability of the Swedish version of the LCI and would only be an appropriate reference if the authors of this case study did indeed use the Swedish language LCI and not the English language LCI5. Similarly, reference 9 refers to assessment of geriatrics and not validity of the IADL for amputees.

Answer: I fixed the citations for the LCI5 studies, and though the IADL has not been scientifically proven valid for use with amputees, I found several instances where it is used clinically to assess amputee status, so I included it for those clinicians.

8.For example, in the abstract, the statement that elevated vacuum "has been scientifically shown to increase the quality of contact between the residual limb and prosthetic socket" is based on only one small study that looked at 5 small areas of localized pressure. Those authors of that study did not discuss their results in terms of "quality of contact" which is an unclear concept.

Answer: The research on EV is sparse and often of extremely poor quality, sometimes actually using just one patient. I changed the wording in the Introduction to reflect the uncertainty about EV's proposed benefits. It's a very new technology, and I did my best to use the highest quality references possible. Part of the purpose of this report is to show that case reports are one way to compile data on EV, but that actual randomized studies are imperative to its clinical adoption.

9.Similarly, on page 7, the authors state that the subject "displayed remarkably symmetrical gait", but what does it mean for gait to be "remarkably" symmetrical. Symmetry is a binary concept: it either was or was not symmetrical. Asymmetry on the other hand can vary in magnitude.

Answer: Fixed, thank you. I was trying to express that it was remarkable that the patient had symmetrical gait, given his previously pathological gait. I just removed "remarkably".

10.The authors state that a score of 44 / 47 on the AMPPro is indicative of a ceiling effect, but that is not the case as the subject did not actually max out the measure.

Answer: Basically, I found a study that you need an increase of 2 points on the AMPPro to show improvement and I was concerned that he came close enough to maxing out the tool for it to be a ceiling effect. Because this reviewer didn't think that it was, I removed that part of the article.

11.There are a number of places where adhoc results are stated that were not described as part of the assessment being reported for this case study. For example, the results of evaluation by a physical therapist are described on page 7 but were not mentioned in the section on treatment and outcome and the manner in which the PT measured weight distribution and gait symmetry are not described.

Answer: I went through the treatment and outcome sections and asserted that the biomechanical changes were observed by the physical therapist and prosthetist. I also added to the first sentence of the Assessment section to show that those observations would be used throughout the process.

12.Specifically, what evidence is there that gait abnormalities, skin irritation and joint pain are common among users of PTB with IWBTC prostheses?

Answer: I added 3 sources to clarify.

	13.What evidence is there that contact dermatitis is caused by pistoning of the socket? Answer: There is actually a lot of fairly good evidence about that, so I added 2 sources about the causes of skin issues. 14.The authors claim that normalizing gait by using elevated vacuum would decrease sound side knee pain and that pain and swelling was gone after one month of use, but it is not clear how pain and swelling were assessed during use of the elevated vacuum prosthesis, although pain was a primary reason given for the transition from the PTB with IWBTC prosthesis. Answer: I amended the explanation about the qualitative interview, since that interview yielded pain and contralateral limb health information. 15.The authors claim that "overall satisfaction with the prosthesis" was dramatically improved but did not actually measure satisfaction with either prosthesis, so what is this claim based on? Answer: I thought I had shown with sufficient strength that the patient's overall satisfaction improved, since his overall function, skin health and pain improved. It's true that I did not quantitatively measure his satisfaction throughout the process, but I feel I did an adequate job through description of the patient's initial dissatisfaction and eventual happiness to say that his satisfaction was dramatically improved. 16.Consent information could be included in the methods. Answer: I think that JPO asks for it to be at the end, at least in the instructions for authors that I read. 17.Table 1 would be improved if it were expanded to provide the actual results of the LCI5, IADL and AMPPro and possibly a summary of the main findings of the qualitative interview at each time point. Answer: I made a second table for the outcomes section. 18.The authors should consider providing a table documenting all the componentry/set up of each prosthesis (original PTB with IWBTC and EV) especially given that the components are obscured by the cosmetic cover in Figure 1. That way the reader can interpret for themselves if other component changes may have contributed to the results since it was not suspension or socket design alone that changed in the transition from one prosthesis to another. Answer: That was included as Appendix i. Reviewer #2 Answer: Thank you, it's my first one.

May 31, 2011

Dear editorial board of the Journal of Prosthetics and Orthotics,

Please find enclosed the manuscript: Using Elevated Vacuum to Improve Functional Outcomes: A Case Report by Erin Sutton, Robert Hoskins and Tyler Fosnight, to be submitted as an original Case Report to the Journal of Prosthetics and Orthotics. All authors have read the contents of the manuscript and approved submission. The authors certify that there are no copyright constrictions, and there is no financial interest to report. We certify that the submission is not under review at any other publication, nor has it been previously published. All three authors were employees of Prosthetic Design, Inc. while this research was being performed. However, the report focuses on elevated vacuum technology overall and not the effects of Prosthetic Design's components, so the authors feel that they did not introduce significant bias. Prosthetic Design, Inc. had no role in the collection, analysis and interpretation of data; writing this report; nor submitting the report for publication. The authors accept full responsibility for the integrity of the work performed.

In this manuscript, we report the results of a case report documenting the functional development of an active transtibial amputee during his transition from a traditional prosthesis to an elevated vacuum prosthesis.

We believe that our findings could be of interest to the readers the Journal of Prosthetics and Orthotics because they could have a great impact on the treatment of amputees experiencing common difficulties with traditional prostheses. Indeed, we found very few studies that documented the effect of elevated vacuum technology on patient functional outcomes. This study will show readers how elevated vacuum was incorporated into a patient's plan of care, how the patient's functional development was measured, and the possible causes of the patient's increased capabilities.

Furthermore, case reports like this one an important step to justify the efficacy of vacuum systems. With qualitative data provided by the prosthetist and physical therapist and quantitative data provided by standard functional assessments, case reports can guide the prosthetic decision-making process and build evidence supporting vacuum use. We hope that the editorial board and the reviewers will agree on the interest of this study.

Sincerely yours,

Erin Sutton on behalf of the authors.

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***Title Page**

Using Elevated Vacuum to Improve Functional Outcomes: A Case Report

Short Title: "Elevated Vacuum to Improve Function: A Case Report"

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Using Elevated Vacuum to Improve Functional Outcomes: A Case Report

ABSTRACT

Elevated vacuum (EV) is a promising technology in the field of prosthetics. It has been shown to improve the fit of the limb in the socket, resulting in many possible benefits to the function of a prosthesis. However, very little research has been done on its effect on patient function. This unique case report was written to document the effect on one patient's function of transitioning from a patella-tendon-bearing (PTB) socket with ischial weight bearing thigh cuff (IWBTC) to prosthesis with an EV socket system. The patient underwent a transtibial amputation as a result of an avulsive trauma and used the PTB socket and thigh cuff for 16 years. In an effort to correct the patient's gait and improve his ability to perform the necessary tasks of his occupation, farming, the patient began using an EV prosthesis. He was interviewed and his functional status was evaluated one week, one month and one year after receiving the prosthesis. After one week the patient showed improvement in skin condition and expressed increased confidence in difficult locomotor tasks. At one month he was no longer experiencing pain in his sound side knee and his gait symmetry had improved dramatically. After one year the patient showed further improvement in gait and balance as well as the ability to wear the prosthesis comfortably for 24 hours at a time when necessary for his occupation. The transition from a PTB with IWBTC prosthesis to an EV system dramatically improved this patient's functional outcome and lessened the negative effects associated with wearing a prosthesis.

KEY INDEXING TERMS: lower limb, prosthetics, function, outcomes, vacuum, sub-atmospheric

INTRODUCTION

It is the goal of all prosthetic interventions to maximize patient function. Research has shown that physical mobility is the only independent factor that significantly affects quality of life in amputees when compared with non-disabled persons.[1] While they theoretically have the highest probability of achieving normal functioning,[2] patients who have undergone amputation due to an avulsive trauma generally have secondary injuries that complicate their recoveries. For transtibial amputees, injuries typically include extensive damage to the patellar tendons and hamstring group. It is possible to accommodate for the resulting gait deficiencies with a patella-tendon weight bearing (PTB) socket connected to an ischial weight-bearing thigh cuff (IWBTC) with external knee joints and check strap (Figure 1). In this type of prosthesis, the external knee joints and check strap combine to prevent knee hyperextension in the PTB socket, accommodating the hamstring group weakness. The forces responsible for hyperextension on the residuum are countered by the check strap.[3]

Alternatively, there is an emerging technology that shows promise as a replacement for traditional prosthesis designs: elevated vacuum (EV). Also known as sub-atmospheric, EV prostheses consist of an elastomeric liner, total surface bearing socket, mechanical or electronic vacuum pump, and a sealing sleeve. Designs can also include an elevated vacuum locking system, a safety feature which provides suspension should the vacuum seal be breached. EV systems have been found to distribute forces evenly over the residuum, so there is an exceptionally high suspension force without the high pressure areas seen in patella-tendon-bearing sockets.[4] It is thought that EV systems maximize surface contact between the socket wall and the liner, enabling high frictional forces that augment suspension and fit. This phenomenon was recently proven in a study of traumatic transtibial amputees where those wearing EV prostheses demonstrated significantly less vertical movement of the tibia during gait

and strenuous activities than those in traditional sockets.[4,5] For a highly active transtibial amputee, intimate socket fit and effective force distribution are integral to the performance of daily activities, as they are imperative to suspension, comfort, proprioception, function, and limb health. Furthermore, a recent study found that skin problems on the residual limb are uncommon with vacuum system users.[6] Finally, one study indicates that EV could enable better stance phase and step length symmetry when compared with PTB designs in transtibial amputees, and the researchers involved explain those results with the fact that EV can provide better total skin surface contact,[7] enabling more mechanical and sensory control over the prosthetic limb. Clearly, EV has the potential to greatly increase patient functional achievement.

Despite the possibilities of EV, the lack of valid research in this area limits the evidence for its use. This fact is highlighted by Van der Linde et al.'s literature review which found a lack of unbiased information about the effects of different components, including sockets, on patient functional status.[8] The vast majority of clinical studies that do exist on the topic have used standardized gait assessment protocols with limited ecological validity, making them inappropriate to use in making a prosthetic prescription.[8] No published reports were found documenting the long-term effect of EV technology on patient function. Very little unbiased, valid research has been found comparing PTB sockets and EV sockets. Therefore, the purpose of this report is to show the long-term functional development of one patient during his transition from a transtibial prosthesis featuring PTB socket, with IWBTC, external knee joints, and check strap to an EV system.

CASE PRESENTATION

The subject in this case is a patient at Dayton Artificial Limb in Dayton, Ohio. He is a highly active 40-year-old male with a left amputation at the transtibial level. His amputation is the result of an avulsive traumatic accident in 1992, in which the patient's limb was caught in a grain augur. The injury caused extensive patellar tendon and hamstring group damage. At the time of reporting in May 2010, the patient was 165 cm tall and weighed 108 kg. He did not smoke and consumed two alcoholic drinks a week. He had not been diagnosed with any other physical health conditions.

Shortly after his amputation, the patient was fit with a PTB socket connected to an IWBTC with external knee joints and a check strap (Appendix i). He was classified a functional level K3 and participated in three months of physical therapy and prosthetic training. He wore this prosthesis for 16 years, with routine fittings and replacements. He required no assistive devices and walked approximately four miles a day on varied terrain as required by his profession as a farmer.

Throughout the prosthetic process the patient reported discomfort around the fibula head, mid-patellar tendon, and at the proximal brim of the IWBTC. The fibula head and mid-patellar tendon area pain were managed with pads and socks, but those areas remained discolored, indicating that they were areas of high pressure. He also exhibited minor but persistent circumduction and gait asymmetry. He began experiencing more difficulties with his prosthesis in January 2010. Specifically, the patient complained of pain and stiffness in his sound side knee joint that were likely due to the gait asymmetry, and his limb displayed contact dermatitis, a condition that can be caused by factors involved in the residual limb and socket interface such as weight distribution and shear force.[9] The negative effects of the prosthesis resulted in its

occasional disuse. The patient expressed a lack of confidence in daily activities like getting down from a tractor, climbing a ladder and walking on uneven ground.

TREATMENT

The patient's residuum was manually examined by the prosthetist in May 2010 at a routine fitting, and his limb displayed increased range of motion and muscle mass compared to the results of similar routine evaluations by the prosthetist since he began using his PTB with IWBTC prosthesis. In a gait evaluation by the prosthetist at that appointment, the patient demonstrated better control of knee hyperextension, and the prosthetist saw increased anterior-posterior and medial-lateral stability in the form of decreased stabilizing motion in the knee joint likely explained by increased muscular compensation. Furthermore, the patient reported a desire to wear a less cumbersome prosthesis that would allow him more freedom of movement. Based on the patient's increased dynamic stability and interest in a new prosthesis, the treating physician ordered an EV prosthesis for the patient. The transition to an EV system was also made in order to simplify the prosthetic use and management for both the patient and the clinician. A total-surface-bearing socket can be fabricated at a central fabrication facility in a matter of hours, compared with the week required to create a custom-laminated PTB socket with IWBTC.

The EV prosthesis included a total surface bearing socket (Prosthetic Design, Dayton OH), silicone liner (Prosthetic Design, Dayton OH), Harmony HD mechanical pump (Otto Bock, Minneapolis MN), EVLS™ suspension (Prosthetic Design, Dayton Ohio), Derma ProFlex sealing sleeve (Otto Bock, Minneapolis MN), and Pacifica foot (Freedom Innovations, Irvine CA) (Figure 2).

ASSESSMENT

To measure the effectiveness of the EV prosthesis in increasing the patient's functional capabilities, he was administered three assessments one week, one month, and one year after he received the EV prosthesis, in addition to routine visual observations of gait and balance performed by the prosthetist and physical therapist (Table 1). An attempt was made to implement the most reliable and ecologically valid instruments for the patient's functional assessment.

First, the patient self-reported his functional capabilities with the Locomotor Capabilities Index 5 (LCI5), a measure of a lower limb amputee's perceived capabilities with a prosthesis. It was originally developed as part of the Prosthetic Profile of the Amputee questionnaire[10] and consists of 14 basic and advanced activities on a five-point ordinal scale. It has demonstrated good internal consistency, test-retest reliability and construct validity when used with adults with lower limb amputation and shows good correlation with the Prosthetic Evaluation Questionnaire's (PEQ) mobility section.[10,11,12] It has been shown to be able to detect changes in functional limitations throughout rehabilitation,[12] making it appropriate for this report. The second assessment was the Instrumental Activities of Daily Living (IADL) index, which is a tool used to measure function in a wide range of patient groups.[13] While not a measure of locomotor ability, it does yield information about a patient's general ability to perform daily tasks. The third assessment was a qualitative interview developed by the clinical facility and used with all patients with questions about residual limb health, sound limb health, hours a day of prosthetic use, pain levels and daily activities.

After one month with the EV prosthesis, the patient completed the Amputee Mobility Predictor with a prosthesis (AMPPro). The AMPPro is a highly reliable instrument designed to objectively measure function in amputee subjects so that clinicians can implement the most appropriate components to achieve an optimal gait.[14] An advantage of the AMPPro is that it provides clinicians with information concerning balance, strength, mobility, agility, and functional limitation needs. It was chosen as an assessment for this report because it has been shown to be a clinically feasible, reliable and valid instrument available for objectively measuring function in amputee subjects.[14,15] Additionally, the AMPPro takes less time and is easier to score than the PEQ.[14] The AMPPro is better able to show effects over time compared to spatiotemporal measures like the six-minute walk test, the ten-meter walk test and the timed up and go test.[15] To show the effect of continued use of the EV prosthesis, the AMPPro was administered for a second time after the patient had been using the EV prosthesis for three months and again after one year of use.

OUTCOME

During the initial fitting session in May 2010, the patient was able to ambulate without aid within five minutes of donning the EV prosthesis (Figure 3). He reported that he liked the stability that it provided around his knee as he walked.

One week after the initial fitting, the patient came in for a final fitting and delivery of the EV prosthesis. He reported that initially blisters developed on the distal end of the residuum as a result of inconsistencies in his donning technique. The sores healed within two days of continued use of the EV prosthesis. The results of the one week, one month and one year assessments are shown in Table 2.

At his one-week appointment, the patient reported in the interview that he wore this EV prosthesis for 10 hours a day with adequate knee joint stability and was feeling more confident with the prosthesis. His residual limb was in excellent condition, with no discoloration or irritation. The patient scored a perfect 56 on the LCI5 and a perfect eight on the IADL index.

One month into use of the EV prosthesis, the patient was again administered the interview and functional assessments. He reported better linkage between the residuum and prosthesis and was not experiencing any inflammation in his sound side knee joint. Gait evaluation by the physical therapist revealed improved symmetry and knee joint stability compared to the one-week assessment, as observed while the patient ambulated in the examination room. The patient stated that he wore the prosthesis for 16 hours a day and walked approximately six miles every day. The patient again received perfect scores on the LCI5 and IADL, demonstrating the significant ceiling effects of those assessments. The patient completed the AMPPro. He scored 44 out of 47 possible points, classifying him as a K4 ambulator. He was unable to stand on his prosthesis side foot unsupported, stand with his eyes closed for 30 seconds or to smoothly vary cadence during the gait tasks.

After one year of use, the patient's functional status was evaluated. In the interview, he reported satisfaction with the EV prosthesis and stated that during the planting season, he was routinely able to wear it for 24 hours a day. He described that he was able to confidently get up and down from his combine, climb ladders and walk over uneven ground in the fields. He displayed symmetrical gait as he ambulated around the examination room, as observed by the physical therapist and prosthetist. His residual limb appeared healthy, with hair-regrowth evident over the entire surface. He again received perfect scores on the LCI5 and IADL. He

scored a 46 on the AMPPro, missing one point for being unable to stand unassisted on his prosthetic foot.

DISCUSSION AND CONCLUSIONS

This patient maintained a high activity level when using the PTB with IWBTC prosthesis, but he was experiencing negative effects, namely gait abnormalities, skin irritation at high pressure areas, and joint pain, effects which are common to lower limb amputees.[6,9,16] These effects resulted in noticeable functional deficiencies expressed in his lack of confidence in more challenging locomotor tasks. Therefore, the clinician's goal was to reduce the negative secondary effects and enable the patient to improve his functional status. Most importantly, it was hoped that the patient would benefit from the gait normalizing effect that had been seen with other transtibial EV patients[4,6,17] which would reduce the stress on his sound side knee. Less vertical movement in the socket could also eliminate the contact dermatitis that he experienced with the PTB with IWBTC prosthesis.[6,9]

The interview and functional assessments allowed the patient's prosthetist to track his development as he became accustomed to the EV prosthesis. His responses and scores indicated that his functional capabilities indeed increased as he learned to use the EV prosthesis. Qualitatively, the patient expressed balance confidence and stability within one week of transitioning from the PTB with IWBTC. This result was unexpected, as it was assumed that the patient would require approximately one month to build up hamstring strength necessary for stability. However, the patient's assertion is consistent with Ferraro's study of transtibial vacuum users[6] and could be due to the high suspension forces possible with vacuum systems.[4] While the LCI5 and IADL assessments were largely unsuited to his high functional level, the

improved balance task performances on the AMPPro suggest that he saw increased proprioception with the prosthesis. This also could have contributed to his confidence during locomotor tasks and explained the high scores on the LCI5.

In addition to balance, his gait normalized throughout the process. He displayed new abilities to vary cadence and display step length symmetry in the first year of use, according to the prosthetist's observations during evaluations, consistent with his improved score on the gait tasks of AMPPro. Most likely these developments were enabled by both the increased range of motion possible without the IWBTC and the increased linkage that he reported between the residual limb and the prosthetic socket, as suggested by Beil.[4] In turn, the pain and swelling in his sound side knee was not reported after one month of EV prosthesis use, since he was able to distribute his weight evenly between his sound leg and the prosthesis.

Significantly, all skin issues were resolved within one week of switching to the EV prosthesis, and his residuum remained healthy even under extreme use conditions. This progress can also be explained by the high suspension forces which kept his limb from moving vertically in the socket[4,5] and is consistent with Ferraro's finding that improved skin health is common in amputees using EV.[6] Furthermore, the areas of high pressure around the fibula head, mid-patellar tendon, and at the proximal brim of the IWBTC had always caused redness on the patient's residual limb when he wore the PTB with IWBTC, and the patient expressed pain at these areas as a result. With the EV prosthesis, the patient's limb was no longer discolored and he reported no pain, supporting Beil's theory that pressure is better distributed in EV prostheses.[4]

With his EV system, the patient was able to walk more, wear his prosthesis longer, climb ladders, jump down from a tractor and traverse uneven ground on a regular basis. For this

patient, the transition from a PTB with IWBTC system to an EV system dramatically improved his functional outcome and overall satisfaction with the prosthesis.

The primary limitation in this case study is the lack of an established baseline for comparison with the PTB with IWBTC. Though this report was primarily concerned with the patient's functional development during rehabilitation with the EV prosthesis, it would have been beneficial to provide quantitative results of the AMPPro and LCI5 for when the patient wore the PTB with IWBTC prosthesis. The patient's performance with the PTB with IWBTC prosthesis was presented qualitatively here as a justification for the transition to EV, but the quantitative data is needed as a baseline. Then, a true comparison of the PTB with IWBTC prosthesis and the EV prosthesis could be presented and this research used more effectively in the broad discussion of the benefits of EV compared to other systems.

Additional work is needed in the use of vacuum in the prosthetic industry. Case reports comprise an important step to justifying the efficacy of vacuum systems, and more are needed that include qualitative data provided by the patient, prosthetist, and physical therapist and quantitative data gathered through standard functional assessments. Furthermore, this patient's outstanding results on the LCI5 were unexpected. The LCI5 is considered a difficult measure appropriate for high-activity amputees, so further research needs to be performed in the area of quantitative gait and balance assessment of high-activity amputees. Finally, additional clinical studies are needed that document the functional development of large numbers of patients as they use EV systems, because such studies would benefit the industry as a whole by identifying technologies that directly improve patient outcomes.

CONSENT

Written informed consent was obtained from the patient for publication of this case report and accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal.

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The authors would like to thank Luci Busch, CPO, of Dayton Artificial Limb Clinic, who contributed skills and materials vital to this research. Additionally, we thank Tracy Slemker, CPO, of Prosthetic Design and Dayton Artificial Limb Clinic, who was critically involved in the editing and publication of this work. Finally, our thanks to the patient who volunteered to be the subject.

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FIGURE LEGENDS

Figure 1. Patella Tendon Bearing Ischial Weight-Bearing Thigh Cuff Prosthesis, check strap not pictured

Figure 2. The EV prosthesis. Component details can be found in Appendix i.

Figure 3. The patient wearing the EV prosthesis.

Figure 1
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Figure 2
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Figure 3
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Table 1

Table 1. Evaluation Schedule

Time Using EV	Assessments
1 week	Qualitative Interview, LCI5, IADL
1 month	Qualitative Interview, LCI5, IADL, AMPPro
1 year	Qualitative Interview, LCI5, IADL, AMPPro

Table 2

Table 2. Results of patient's assessments

Time Using EV	LCI5 __/56	IADL __/8	AMPPro __/48	Qualitative Interview - Summary
1 week	56	8	n/a	10 hrs/day, adequate knee stability, no irritation, no contralateral pain
1 month	56	8	44	16 hrs/day, better linkage, no swelling or pain in contralateral knee joint
1 year	56	8	46	Occasionally 24 hrs/day, hair re-growth, confident in stability at work, no pain

Appendix i

Click here to download Supplemental Data File (.doc, .tif, pdf, etc.): Sutton Appendix i.docx

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