

# TOWARDS A NEW GENERATION OF PROSTHESES

## FROM RESEARCH TO RETAIL

### INAUGURAL LECTURE

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# **Towards a New Generation of Prostheses: From Research to Retail**

## **Inaugural Lecture**

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Perpustakaan Universiti Malaya



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# Biography of the Author

Prof. Ir. Dr. Noor Azuan Abu Osman graduated from University of Bradford, UK with a B.Eng. Hons. in Mechanical Engineering, followed by MSc. and Ph.D. in Bioengineering from University of Strathclyde, United Kingdom. Prior to joining UM, Azuan worked as M&E Engineer in construction Industries.

During the early years in UM, he has taught in the fields of biomechanics, prosthetics and orthotics and in the broad area of mechanical and biomedical engineering. Azuan has played a key role in promoting biomedical engineering prosthetics and orthotics education in Malaysia and the pioneer who founded the Bachelor degree program in Biomedical Engineering (Prosthetics and Orthotics) in response to the demand in Malaysia for engineering techniques that could improve the quality of life of disabled individuals.

Azuan's research interests are quite wide-ranging under the general umbrella of biomechanics. However, his main interests are the measurements of human movement, the development of instrumentation for forces and joint motion, and the design of prosthetics, orthotics and orthopedic implants. He has received over RM12 million in collaborative research grant support and completed within the time frame allocated without any compromise on quality and it is on the assessment panel of national and international granting bodies. To sustain his world-class research, he has established an extensive network with peers and experts from many top-notch universities including Strathclyde University, Calgary University, Melbourne University, Hong Kong Polytechnic University, Rehabilitation Institute of Chicago, and many others. His extensive experience in supervision has made him successfully graduated 15 PhD and 22 MEngSc (Master by research) students.

Through his dedication in research activities, he has won many awards and recognition from various organizations. Among the best awards, in 2004 he received BLESMA award from ISPO UK NMS in recognition of his significant contribution to the development of the prosthetic socket. In 2013, he received "The Forchheimer Prize" the most prestigious prize in the field of Prosthetics & Orthotics from International Society of Prosthetics and Orthotics, for his research contribution to the world of prosthetics. He has to-date published more than 180 articles in ISI high impact journals and authored 3 engineering academic books (Motion Analysis System An Integrated Approach (2009), Motion Analysis System (2001) and An Integrated Approach for 3D Model (2010). He has delivered more than fifty keynote, plenary and invited talks at international conferences, symposiums and workshops regarding prosthetics technologies in biomedical engineering all over the world.

Besides his contribution in research and teaching, Azuan is actively involved in many consultancy projects, especially in the field of biomechanics and bio-mechanical engineering and acted as principal investigator in industrial projects with several reputable international and national organizations. He is currently the Deputy President of Society of Medical and Biological Engineering (MSMBE), affiliated organisations of International Federation for Medical and Biological Engineering (IFMBE). He was also active in promoting University expertise to government and private sectors through his appointment as one of the board member of the University of Malaya Consultancy Unit.

He is also a Professional Engineer (PEng) with Board of Engineer, Malaysia, Chartered Engineer (C.Eng.) and Fellow (FIMEchE) with The Institute of Mechanical Engineers, UK, Chartered Professional Engineer (C.PEng) and Fellow (FIEAust) with Engineers Australia and Fellow of Academy Science of Malaysia (FASc).

At the managerial level, he is currently the Dean of Engineering, the Deputy Director of Centre for Applied Biomechanics and the Coordinator of Motion Analysis Laboratory, Faculty of Engineering, University of Malaya. His valuable contribution continues at the government level, where his expertise in the field of biomechanics has been recognized through his appointment as the leader and chairman of the project to establish the Engineering Standard Practice of National Occupational Skills Standards for Prosthetist/Orthotist Rehabilitation Engineers and Prosthetic/Orthotic Technologists. The standard has been approved and endorsed by the Malaysian government and is used by its Ministry of Human Resources. Azuan also served as Technical advisor for Majlis Amanah Rakyat and the Chairman of Hala Tuju Prostetik dan Ortotik Malaysia.

To this end he wholeheartedly recognize the importance of working closely with other engineers, scientist and scholars and he dedicated a significant amount of time to fostering relationships that can offer real long-term benefits to all parties involved and also to the nation.

**Dedicated to**

*My beloved family, wife Liana and children Nadia, Erwin & Natli.*

*To my wife for her continuous support and encouragement*

*To my children, I hope this will inspire them and lead successful lives*

University of Malaya

# Abstract

Suspension systems and sockets are some of the critical components in prosthesis. Excessive translation, rotation, and vertical movements between the residual limb and socket should be prevented through the suspension system. Good prosthetic suspension system secures the residual limb inside the prosthetic socket and enables easy donning and doffing. Prosthesis suspension systems can alter the distribution of pressure within the prosthetic socket and poor suspension increases slippage of the residual limb inside the socket during ambulation. In this most grueling test of the technology to date, we demonstrated that our advanced research is quickly on its way to becoming a new generation of prostheses. Originally developed at Faculty of Engineering, University of Malaya, The Magnetic Suspension System and Prosthesis Liner are among the new technology, as the result of research from the Centre for Applied Biomechanics (CAB). Prosthetic suspension system is on track and successfully commercialized the first phase of the technology through BioApps Sdn Bhd, University of Malaya Spin-off Company in early 2015. Further development of the prosthetic suspension and stability system is underway, as it represents the next step required to fully restore lower-limb amputees' complete biological function. The new generation of prostheses suspension system could successfully retain the prosthesis on the residual limb as a good alternative for lower limb amputees. In addition, the new system addresses some problems of the existing systems and is more cost effective than its counterparts.

# Acknowledgement

Alhamdulillah and most grateful to the Almighty for granting me to be here through this career until now. I am very much thankful to Professor Dato' Dr. Mohd Amin Jalaludin, Vice Chancellor for his guidance, keen interest, and encouragement until now.

I would like to express my appreciation to all the collaborators from various departments, universities, and agencies. These collaborations are really meaningful for me which enabled my research team to carry out the research. I really appreciate for all the cooperation and kind help given.

A special thanks to the research team, Co-Pi's, post-doctoral researchers, researchers, postgraduate students, undergraduate students, engineering management staffs, faculty members, CAB staffs, BioApps staffs, and any person who took part and involved in my research projects. Your contribution to this area is highly appreciated.

I also want to say big thank you to all patients who are always enjoy to be my research subjects. Your positive spirit and contributions are so special and encourage me to complete this research.

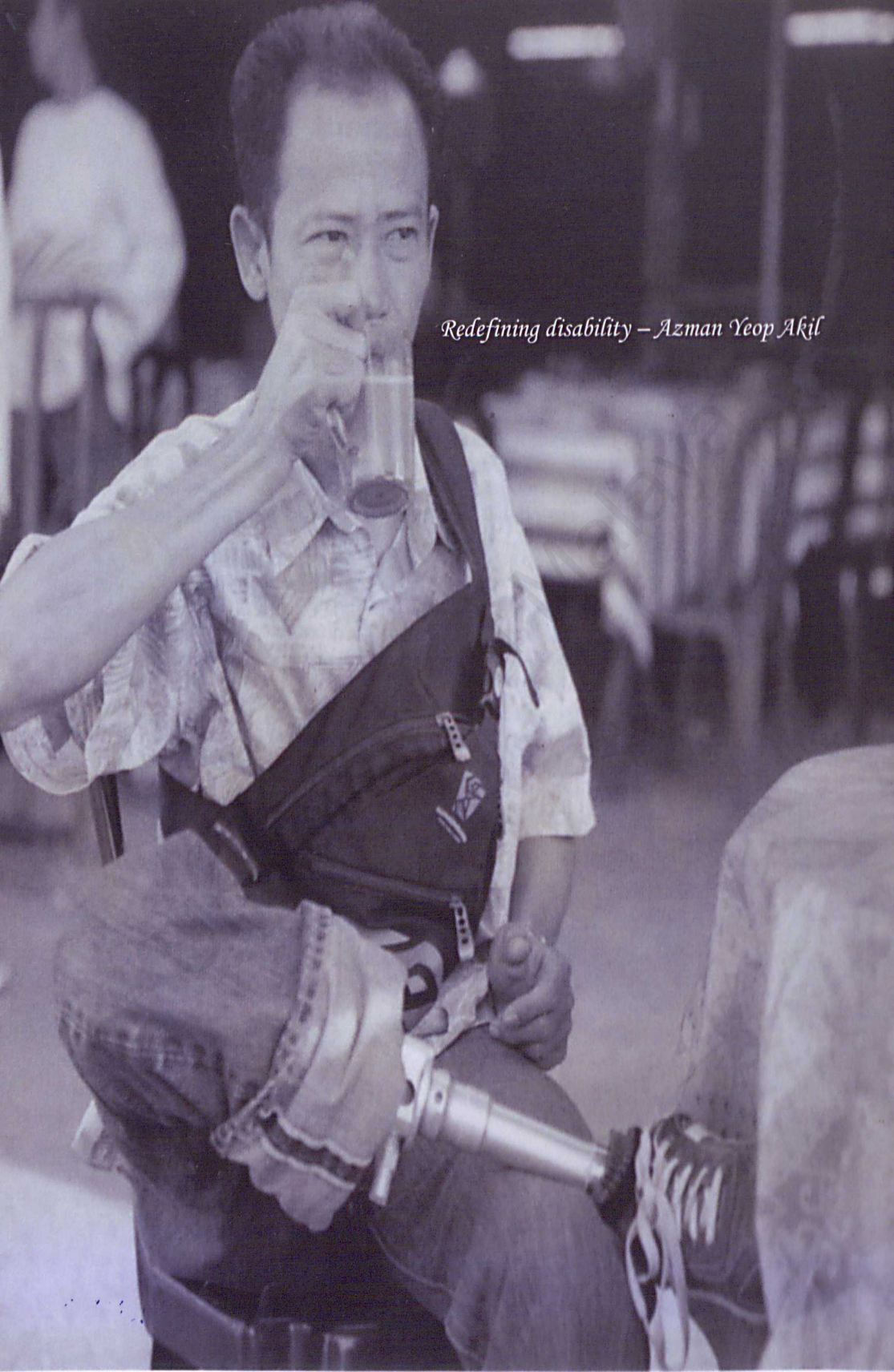
Last but not least, to all my friends, colleagues, mentors, which cannot be contained in this list I say a big thank you. Wherever you are, your support and friendship are always remembered.

*Prof Ir Dr Noor Azuan Abu Osman*

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*Redefining disability – Azman Yeop Akil*

## 1. Introduction

Lower limb loss is mainly caused by trauma, diabetes, tumors, congenital limb deficiency, and peripheral vascular disease (PVD) [1]. According to Smith [1] lower limb amputation is mainly the result of PVD worldwide, which is frequently linked to diabetes mellitus. Prosthesis or artificial limb is the foremost element in the rehabilitation process of limb loss.

Prosthetic components and systems have been evolved tremendously in the recent decades to the level that amputees can even participate in the Olympic Games! However, even with key advances in prosthetic device research and development, still many amputees are reluctant to use prostheses due to various physiological and psychological problems. Therefore, the development of new prosthetic systems would be beneficial to overcome current prosthetics drawbacks which will in turn results in higher satisfaction with the artificial limbs.

When lower limb prosthesis is in use, the lower limb residuum is required to bear weight, but its soft tissues are not physiologically accustomed to such weight bearing activities [2,3]. Therefore, advancements in prosthetics technology are of utmost importance to amputees' life. Lower limb residuum should bear weight while its soft tissues are not physiologically accustomed to weight bearing. Individuals with lower limb amputation need a secure suspension system for their prosthetic devices. A new coupling system was developed that is capable of suspending the prosthesis.

This study explains how the system works and provides an in vivo evaluation of the device with regard to pistoning during walking. The system was designed to be used with silicone liners and is based on the requirements of prosthetic suspension systems. The pistoning during walking was measured using a motion analysis system. The new coupling device produced significantly less pistoning compared to a common suspension system (pin/lock). It could securely suspend the prostheses in transtibial amputees and produced less vertical movement than the pin/lock system.

## 2. Suspension System

The suspension system and socket fitting in prosthetic devices significantly affect the amputee's comfort, mobility, and satisfaction [4,5] Secure suspension decreases residual limb movement within the prosthetic socket by firmly attaching the prosthesis to the residual limb [6]. Conversely, inappropriate suspension can result in deterioration of the prosthetic socket fitting, and a poorly fit socket can cause pain and skin ulcers. These problems may result in unwillingness or an inability of the amputee to use the prosthesis until the pain is relieved and the ulcers are healed [7-9].

There are several methods of suspending a transtibial prosthesis to the residual limb [10]. These include the following:

- i. Belt and suprapatellar cuff, which is the most common suspension method and usually the most effective for most wearers [11]
- ii. Figure-of-8 belt, which is a variation of the suprapatellar cuff suspension
- iii. Sleeve suspension, which can develop negative pressure between the socket and residual limb [12,13]
- iv. Supracondylar-suprapatellar suspension [14]

- v. Supracondylar suspension, which is a variation of supracondylar-suprapatellar suspension and is usually used for long residual limbs [15]
- vi. Thigh corset, which provides more mediolateral stability for the users [16]
- vii. Silicone liner suspension, such as distal locking pin, lanyard, and suction suspension [17]

Patellar tendon-bearing prostheses with polyethylene foam liners have been in use since 1950. They are fitted within the socket to provide the residual limb with a soft cushion. Polyurethane foam liners are still used in practice, but modern liners are generally made from silicone and other elastomers that offer better suspension and cushioning. Silicone and gel liners were introduced worldwide in the mid 1990s and were designed to lessen shear forces and produce a better interface bond. A new type of silicone liner, called the seal-in liner, uses a membrane lip, which is placed circumferentially around the distal end of the liner.

Every lower limb prosthesis for persons with lower limb amputation is consisted of the following components but not limited to: socket, pylon (shank), knee and foot. The prosthetic suspension system is usually positioned either inside the socket or between the prosthetic socket and the pylon. Considering the limited space available at this interface, the dimensions of the coupling system used in this study were designed so that it could fit the socket end of an adult amputee. The limited space also dictated the height of the coupling system so that it could also be used with long residual limbs. The new system was designed to be used with silicone liners as they are widely available and commonly in use. To this end, a cap was designed that matched both the main body of the new coupling device, and the liner's distal end. The dimensions were purposely formulated to match with those of the liner. The cross section was circular and, in order to reduce weight, the cap was hollow. The hollow space incorporated a central screw in the middle and was filled with silicone adhesive to promote firm attachment to the liner. The new coupling idea was based on the magnetic field. As such, the cap was made of mild steel to produce high gripping force.

The body of the coupling device was the source of magnetic power. A permanent Neodymium Iron Boron magnet was utilized that was small but was capable of generating a strong magnetic power. The housing intensified the magnetic field by flanges. In order to control the magnetic power, a mechanical switch was affixed to the housing and the magnet. When the rotary switch was in the "On" position the cap was attracted to the housing, whereas it was released from the lower body of the coupling device when the switch was in the "Off" position.

A coupling alarm system was designed that is capable of detecting any failure in the newly designed coupling system for the lower limb prosthesis. This system consists of an interface; process unit and power supply (Figures. 1, 2). The signals are detected and processed through a micro-controller unit that subsequently makes the appropriate decision as to whether to energize the output or not. The interface consists of two inputs and one output. One hall-effect sensor detects the magnetic field and a contact sensor ensures that the joint remained in total contact with the limb. The output is a buzzer which is energized through a transistor to amplify the microcontroller signals and produce the

required alarm. The buzzer produces an audible alarm signal at the level of 97dB with the frequency of 2 KHz.

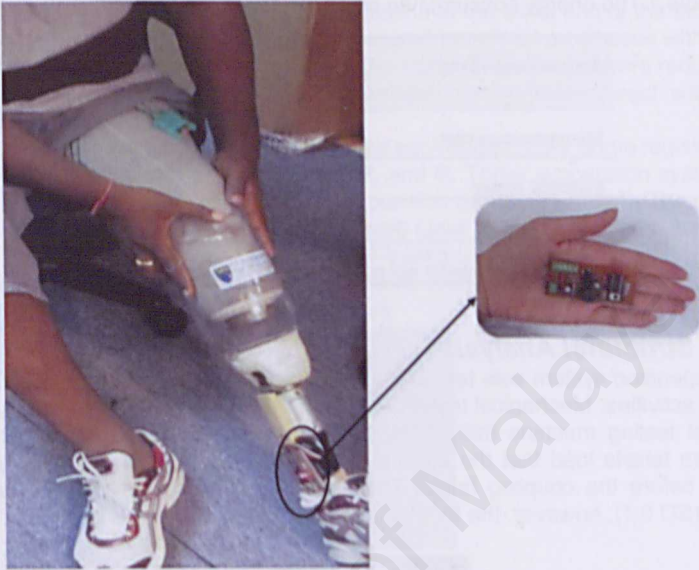


Figure 1. New prosthetic coupling system. A participant is donning a prosthesis that is fitted with the new prosthetic coupling system and the coupling alarm.

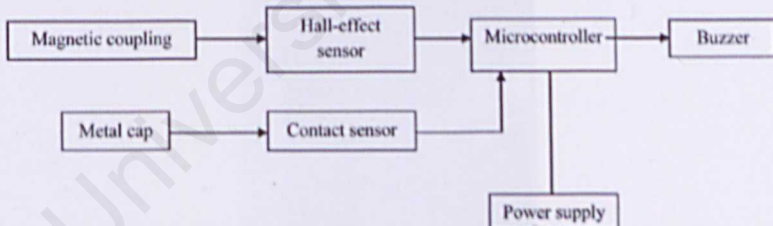


Figure 2. Alarm system. Block diagram of the coupling alarm system.

Power in the range of 2.5 to 5V was required for the microcontroller. The buzzer and Hall-effect sensor required a 9V battery. Therefore, a 9-Volt battery, a 1V regulator and two transistors were utilized. The transistors are responsible for switching the voltage between the microprocessor output and the desired voltage for the Hall-effect sensor and buzzer. The microprocessor is required to distinguish whether the coupling is successfully attained or had failed. If the signals from the Hall-effect sensor show that the magnetic field has activated the coupling, the contact sensor signals are analysed.

The microcontroller samples every one millisecond for 3ms. If all data are the same, it would be replaced by the previous. This process is also repeated for three times to ensure that the sensor detected the vibration of coupling; not the detachment. The final result will be processed by the microprocessor to make

appropriate decision. This device is equipped with one 1200 mAh 9V battery. Energy consumption of different parts is shown in table 1.

Table 1 The energy consumption of different components of the alarm system.

System component	Energy consumption ( $\mu$ A)
Microprocessor unit	15 (in work mode) 2 (in standby mode)
Magnetic sensor	10
Buzzer	700 (in alarm mode)
Other parts, transistors and regulators	500

## 2.1 Structural Analysis

The suspension system was tested mechanically as the subjects engaged in basic walking activities. Mechanical testing under tensile loading was performed using the universal testing machine INSTRON 4466 through a special jig (Figure. 3). The maximum tensile load that the system could bear was 350.9N (SD 0.5) of tensile loading before the coupling failed. The pin/lock system could tolerate loading of 580.4N (SD 0.1); however, the lock system lost its function after three trials.



Figure 3. Tensile testing for the new prosthesis coupling system.

## 2.2 Motion and Gait Analysis

The clinical test protocol was approved by the Medical Ethics committee, University of Malaya Medical Centre (Reference No. 907.26). The new magnetic suspension was assessed on ten male individuals with transtibial amputation. The inclusion criteria were unilateral transtibial amputation, activity levels of K2-K3 according to the

American Academy of Orthotists & Prosthetists [18]. Residual limbs free of wound and pain, no upper limb disability, experience with silicone liners, no volume fluctuation in the residual limb, and the ability to ambulate independently. The stump length, measured from the inferior edge of the patella to the distal end of the stump, had to be no less than 13cm. All the participants used transtibial prostheses with pin lock suspension system prior to the initiation of the study. The subjects were required to sign a consent form to enter the study and the researchers considered each subject as his own control.

Three prostheses were fabricated for each subject by a single registered prosthetist to ensure uniform design, alignment, and fit. Three suspension systems were selected, including the new lower limb suspension design (Figure. 4). The other two systems were a) shuttle lock and pin (Dermo® Liner with Icelock-clutch 4 H214 L 214000) and b) the suction suspension (Seal-In®X5 Liner with Icelock Expulsion Valve 551). Other prosthetic components were common between the three prostheses (Flex-Foot Talux® and Tube adaptor).

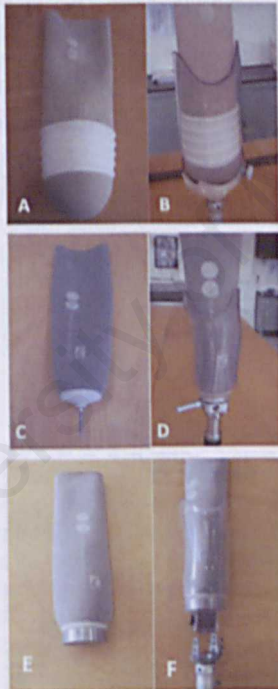


Figure 4: Three suspension systems used in this study. A, Seal-In X5 liner; B, transparent socket and valve; C, Dermo liner with pin; D, transparent socket and shuttle lock; E, Dermo liner with distal cap; F, transparent socket and new magnetic lock.

Transparent thermoplastic material ensured that the sockets were Total Surface Bearing (TSB) [19] and had visible walls, through which the researchers could detect the internal features. The processes of checkout, gait evaluation, and gait training were performed in the Brace & Limb Laboratory, University of Malaya. Furthermore, the Prosthetic Evaluation Questionnaire (PEQ) required at least one-

month of prosthetic use for each prosthetic type to allow for adaptation to new prostheses.

The mean age, height, and weight of the participants were 42 years (SD, 12.8), 172cm (SD, 5.1), and 79.5kg (SD, 12.2), respectively. The cause of amputation was either diabetes or trauma. The average prosthetic mass for suction, pin and lock and new prosthetic suspension system among the ten subjects was 1.75, 1.86 and 1.92kg, respectively. The intraclass correlation coefficient (ICC) of intra-observer intersession and inter-observer intersession and intra-observer intrasession were 0.80 and 0.72 and 0.93, respectively.

After the completion of four weeks of prosthetic use for each system, the subjects attended the motion laboratory for quantitative study. The order of prosthetic suspension system use was randomized for every subject. In order to investigate the pistoning inside the prosthetic socket, researchers adopted the static method using a 7-camera Vicon 612 motion system (Oxford Metrics; Oxford, UK). Sixteen reflective markers of 5mm diameter were attached to each subject's prosthetic and sound lower limbs according to the Helen Hayes marker set. The lateral distal end of the socket and the lateral proximal socket wall were selected to locate the tibia and knee markers on the prosthesis, respectively. As it was attempted to measure the pistoning between the liner and socket, two extra markers (paper-thin) were attached to the liner under the functional knee joint level and 5cm below that. The accuracy level of the motion analysis system was less than  $\pm 0.1$  mm [20].

The subjects stood on a platform. The researchers measured the pistoning by the gait simulation method through load application [19,21-23]. Double limb and single limb support with the prosthesis were considered compressive loadings. The subjects were required to perform single-limb stance on the prosthetic limb (full weight bearing). Then they stood on both limbs to fulfill the semi-weight bearing step. For tensile loading, the subjects had to hang their prosthetic leg from the platform edge (non-weight bearing). Next, three loads of 30, 60, and 90N were added consecutively to the prosthetic foot. The swing phase of gait has been previously replicated by similar loads [19,21-23]. In order to determine the pistoning, the distance between the markers on the liner and on the socket was calculated in each loading condition.

### **2.2.1 Qualitative Evaluation**

The PEQ questionnaire is a self-report instrument commonly used to evaluate prosthetic users' satisfaction with prostheses. The original version is subdivided to 9 sections comprising of 82 questions. As the questions are not dependent on each other, it is possible to use them as appropriate to a given study [25]. For the qualitative analysis, a questionnaire was designed that utilized selected questions of the PEQ under scales of demographic data, satisfaction and problems. The subjects completed a separate questionnaire for each prosthetic type after they finished four weeks of prosthetic use. The questionnaire included the following three scales:

- i. Demographic data (age, cause of amputation, weight, height, and time since amputation)
- ii. Satisfaction (fitting, sitting, ability to walk on level surface, uneven ground, up and down the stairs; cosmesis; suspension; don and doff; overall satisfaction)
- iii. Problems (sweating, wound, skin irritation, pain, pistoning within the socket, residual limb rotation inside the socket, swelling, unwanted sounds and bad odour).

There was a significant effect for the suspension type among all the questions of the questionnaire,  $F(2, 18) = 153.18$ ,  $P = .000$ . The questionnaire survey revealed that the overall satisfaction rate with the magnetic system was higher than the pin lock and suction systems ( $P < 0.05$  for both comparisons). Donning and doffing were easier with the magnetic suspension system compared with pin lock system (mean score: 79.68 vs. 71.44;  $P = 0.000$ ) and suction system (mean score: 79.68 vs. 57.24;  $P = 0.000$ ) with 95% confidence intervals. Subjects stated that they were more satisfied during walking and stair climbing with the new magnetic system over two other systems ( $P < 0.05$  for both comparisons). Suspension satisfaction with the new magnetic system was similar to the pin lock system ( $P = 0.062$ , two tailed), while the suction suspension resulted in higher satisfaction score in comparison to the new system ( $P = 0.000$ ). The statistical analysis showed significant differences in some of the complaint/problem items ( $P < 0.05$ ) among the three suspension systems. Pain score with the new magnetic system was significantly less than the pin lock suspension (90.18 vs 70.62, respectively;  $P = 0.000$ ). Also, problems with the unwanted sound was higher with the pin and lock system compared with the new system; however, the subjects experienced less unwanted sound with the suction system than the new system ( $P < 0.05$  for both comparisons).

### 2.2.2 Quantitative Evaluation

The main effect of the suspension type in adding and removing ( $F(2,18)=124.11$ ,  $P=0.000$ ) through ANOVA demonstrated a significant difference between the three suspension systems. There was also significant difference between different positions of adding and removing ( $P=0.000$ ). Therefore, paired-samples t tests were used to determine significant differences between each pair of suspension systems. When the base measurement at full weight bearing was compared to the peak pistoning at 90N loading, the new magnetic system caused approximately the same amounts of pistoning as the pin and lock ( $P=0.086$ ). However, the suction system (Seal-In@X5) showed less pistoning compared with both the pin and lock and new magnetic system ( $P < 0.05$  for both comparisons). From semi to non-weight bearing, mean pistoning was lower with the new magnetic lock than the pin lock system ( $1.0\pm 0.6\text{cm}$  vs.  $1.5\pm 0.5\text{cm}$ ;  $P = 0.016$ ), while the new magnetic lock had higher mean pistoning in comparison to the suction suspension ( $1.0\pm 0.6\text{cm}$  vs.  $0.2\pm 0.1\text{cm}$ ;  $P=0.007$ ). When 30N load was added, significant difference was seen in the displacement with the new magnetic lock compared with the pin lock system as the new lock resulted in less displacement ( $P=0.004$ ). Conversely, less pistoning occurred with the suction system than the new magnetic lock ( $P=0.000$ ). Same significant differences were seen in the pairs of magnetic-pin lock and magnetic-suction system when 60N loads were added (both  $P<0.05$ ). Table 2 presents the mean displacements between the liner and hard socket with the three suspension types under different static conditions (adding and removing loads). As we expected, the pistoning reduced in the process of removing the loads for all the three systems. Nevertheless, the reduction did not follow the same trend that was found during the adding procedure, as significant differences were found between the pistoning values in adding and removing (for 30N, 60N and non-weight bearing) when each system was individually studied. Figure 5 illustrates the mean pistoning values ( $\pm$ SD) in each weight-bearing condition for three studied suspension systems.



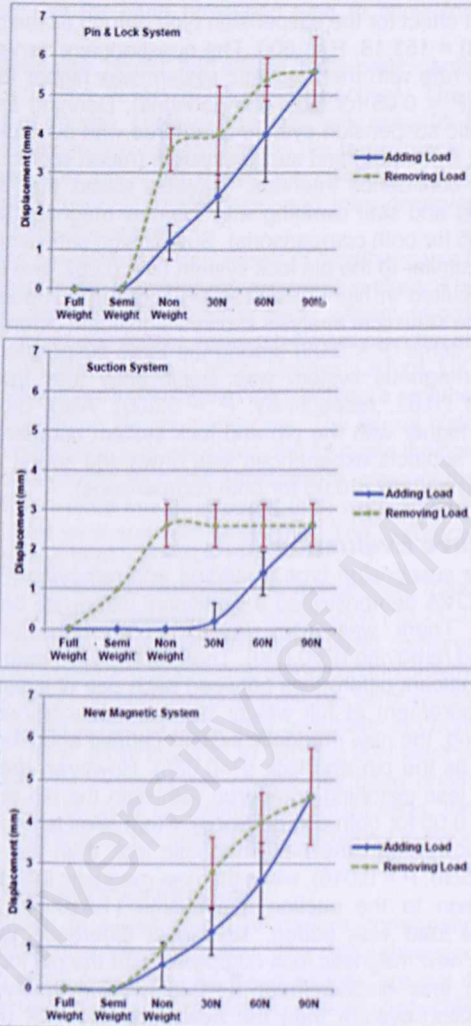


Figure 5: Pistoning results for adding and removing loads in static positions for three suspension systems. (n = 10; displacement  $\pm$  standard deviation).

Table 2. Mean pistoning values of three suspension systems in different static positions during adding and removing loads (n=10). All values are in millimetre.

	Adding Load										Removing Load														
	FWB		SWB		NWB		30N		60N		90N		ANOVA		30N		60N		90N		ANOVA				
	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)			
Sections <sup>1</sup>	0	0	0.2(0.1)	0.9(0.4)	1.7(0.5)	2.8(0.5)	0.000*	2.8(0.5)	2.6(0.5)	2.6(0.5)	2.6(0.5)	2.6(0.5)	0.000*	2.6(0.5)	2.6(0.5)	2.6(0.5)	2.6(0.5)	2.6(0.5)	2.6(0.5)	2.6(0.5)	2.6(0.5)	2.6(0.5)	0	0.000*	
Magnetic Lock <sup>2</sup>	0	0	1.0(0.6)	2.0(0.5)	3.3(1)	5.3(0.7)		5.3(0.7)	4(0.7)	4(0.7)	4(0.7)		4(0.7)	4(0.7)	4(0.7)	4(0.7)	4(0.7)	4(0.7)	4(0.7)	4(0.7)	4(0.7)	4(0.7)	0	0	
Pin Lock <sup>2</sup>	0	0	1.5(0.5)	2.7(0.7)	4.3(1.1)	5.8(0.8)		5.8(0.8)	5.4(0.5)	5.4(0.5)	5.4(0.5)		5.4(0.5)	5.4(0.5)	5.4(0.5)	5.4(0.5)	5.4(0.5)	5.4(0.5)	5.4(0.5)	5.4(0.5)	5.4(0.5)	5.4(0.5)	0	0	
Significance (two tailed)			1-2 (0.007)	1-2 (0.000)	1-2 (0.000)	1-2 (0.000)		1-2 (0.000)	1-2 (0.000)	1-2 (0.000)	1-2 (0.000)		1-2 (0.000)	1-2 (0.000)	1-2 (0.000)	1-2 (0.000)	1-2 (0.000)	1-2 (0.000)	1-2 (0.000)	1-2 (0.000)	1-2 (0.000)	1-2 (0.000)	1-2 (0.000)	1-2 (0.000)	1-2 (0.000)
			1-3 (0.000)	1-3 (0.000)	1-3 (0.000)	1-3 (0.000)		1-3 (0.000)	1-3 (0.000)	1-3 (0.000)	1-3 (0.000)		1-3 (0.000)	1-3 (0.000)	1-3 (0.000)	1-3 (0.000)	1-3 (0.000)	1-3 (0.000)	1-3 (0.000)	1-3 (0.000)	1-3 (0.000)	1-3 (0.000)	1-3 (0.000)	1-3 (0.000)	1-3 (0.000)
			2-3 (0.016)	2-3 (0.004)	2-3 (0.002)	2-3 (0.000)		2-3 (0.000)	2-3 (0.000)	2-3 (0.000)	2-3 (0.000)		2-3 (0.000)	2-3 (0.000)	2-3 (0.000)	2-3 (0.000)	2-3 (0.000)	2-3 (0.000)	2-3 (0.000)	2-3 (0.000)	2-3 (0.000)	2-3 (0.000)	2-3 (0.000)	2-3 (0.000)	2-3 (0.000)

SD=standard deviation; FWB=full weight bearing; SWB=semi weight bearing; NWB=non weight bearing. \* indicates significant differences among the three suspension systems from the Repeated measure ANOVA. "1-2", "1-3" and "2-3" indicate that significant differences (P<0.05) were found between each two suspension systems in each loading position based on the paired-samples t tests

When evaluating our hypothesis regarding the difference between the pistoning with pin lock and magnetic system, pistoning appeared comparable from full weight bearing to 90N for the pin lock system and the magnetic suspension. The statistical analyses revealed higher peak pistoning with the new magnetic system in comparison to the suction system from full weight bearing to addition of 90N load ( $P < 0.05$ ). Researchers have performed various evaluations of piston motion with a variety of prosthetic sockets and soft interfaces. Studies have found that TSB sockets with silicone liners result in significantly less piston motion between the liner and socket [22,25]. In the current study, the suction system (Seal-In@X5) system resulted in the least pistoning among the three systems, which supports the findings of Gholizadeh et al. (2011) [5]. Mean pistoning with the pin lock system from full weight bearing to 90N was 5.8mm (SD, 0.6), which is similar to the results of Tanner and Berke (2001), Board et al. (2001) and Gholizadeh et al. (2011) [22,23,26].

None of the three studied systems demonstrated pistoning movement from full to semi-weight bearing which is not surprising as in the full weight bearing position, the limb moved distally in the socket and large force was developed between the liner and socket that restricted pistoning strongly. Slight differences were seen in the systems' behaviors between adding loads and the reversed process of loading (removing loads), particularly for the suction system (Seal-In@X5). The mean pistoning values for 60N, 30N and non-weight bearing did not statistically approach the same that were seen during adding loads (non-weight bearing, 30N and 60N) when each suspension system was individually studied ( $P < 0.05$  for all three systems). The exception was that with the suction system, no significant difference was seen between each single step from 60N to non-weight bearing. This denotes a delay in the process, which might be associated with the increased friction and suction between the Seal-In@X5 and the socket wall (Figure 5). Nevertheless, further research is needed to prove this assumption.

One of our findings was that there will be significant increase in satisfaction rates with the new suspension system than the other two systems. All three suspension systems studied in this research showed approximately high satisfaction rates among the participants. Nevertheless, the qualitative survey demonstrated significant differences in satisfaction and perceived problems with the new design compared with the pin lock and suction systems. The new magnetic suspension system resulted in higher satisfaction scores than pin lock and suction systems only on a number of items.

The new magnetic suspension system seems to be similar to the current systems in function as it can retain the prosthesis on the residual limb during ambulation. Furthermore, the new suspension system produced less noise during walking and donning compared with the pin lock suspension ( $P = 0.003$ ), was much easier to don and doff compared to the suction suspension and pin lock system ( $P < 0.05$  for both), and resulted in higher overall satisfaction in comparison to both suction and pin lock systems ( $P < 0.05$  in both cases). Vacuum suspension is said to improve proprioception in prosthetic users [27]; however, our subjects stated preference to the magnetic lock over the suction system. The pin lock system resulted in higher satisfaction than the suction suspension (Seal-In@X5) system, which is consistent with the results of Gholizadeh et al. [19,22].

To compare the new magnetic suspension system to the pin lock suspension, the undesirable noise of locking systems was significantly lower, while the amputee still felt secure from the audible feedback of the primary contact between the distal and proximal portions of the new system. Amputees can use the new system with their old liners as the cap is attached to the liner by silicone adhesive and

a screw which is similar to the screw diameter for most of the locking silicone liners in the market. However, the socket needs to be replaced to embed the distal part of the new magnetic system at the distal end of the socket.

Our subjects reported that they felt more secure with the new system compared to the pin lock suspension. They believed that with the pin lock system they felt like they were walking on an unstable moving rod (pin), while when they walked with the new system they experienced a firm, stable base of support under the residual limb. That might be associated with the cross-sectional difference between the single pin (the pin lock system) and the cup-shaped cap of the new system. Nevertheless, their subjective reports revealed that suction system resulted in higher confidence during walking which is consistent with the study by Gholizadeh et al.[19] that the participants reported they felt the leg with the suction system to be a normal part of their body. The cosmesis of the new system was almost the same as the pin lock system ( $P = 0.185$ ). Conversely, the subjects were more satisfied with the suction system compared with the new magnetic system in terms of cosmesis which can be attributed to the added components. Additionally, the same problem of the pin lock system may arise with long stumps due to limited space below the socket for installation.

Effortless donning and doffing appears to result in higher overall satisfaction [28,29]. The Seal-In®X5 liner has solved some of the problems with pin lock systems; however, patients still require more time and effort when donning and doffing. They also need to use lubricant sprays (Clean & Simple Lubricant spray, Össur) to facilitate donning process of both the liner and the socket. Moreover, hand dexterity is more critical for donning and doffing a Seal-In®X5 liner compared with the Dermo® liner. Rolling the Seal-In®X5 is more difficult as the seals do not smoothly slide over each other unless some lubricant spray is used. The subjects of this study were mainly dissatisfied with donning and doffing of the Seal-In®X5 system; donning and doffing was significantly easier with the magnetic system. Meanwhile, our subjects experienced less pistoning and rotation within the prosthetic socket with the suction system compared with the new magnetic lock which is consistent with the results obtained from the pistoning measurement by motion analysis system. Subjects stated preference for the new magnetic system over the Seal-In®X5 and pin lock for long-term use.

Some patients have trouble aligning the pin when donning the prosthesis. In the proposed system, the distal and proximal components at the distal end of the liner and socket are easily connected as soon as the residual limb is located into the hard socket. The total contact fit also deteriorates, especially if the residual limb is pointed and bony. The new system might resolve the so-called problem of "milking" or distal tissue stretching caused by the pin and lock. This milking phenomenon can also result in pain, particularly at the end of the tibia and along the tibial crest. Pin lock suspension is said to have short- and long-term negative effects on the residual limb. Short-term effects are discoloration and swelling at the distal end of the residual limb which will result in the change in soft tissue shape, skin thickness and color in long term. These changes might be the result of liner elongation which develops milking. As a result, the residual limb is compressed at the proximal end and stretches the distal soft tissue, particularly during the swing phase [30]. Nevertheless, further studies are needed to investigate the effect of this new system on milking.

### 2.2.3 Interface Pressure

In order to check the interface pressure, four F-Socket transducers 9811E (Tekscan Inc., South Boston, USA) were employed. It is generally accepted that the sensors used to measure for interface pressure should be as thin as possible (Kim et al., 2003). The paper-thin F-socket sensors had a thickness of 0.18mm, good flexibility and high resolution. The sensor mats were trimmed according to the residuum counters and were located on the anterior (Ant), posterior (Pos), medial (Med) and lateral (Lat) surfaces of the residuum. In order to avoid displacement, adhesive spray (3M Spray Mount Adhesive, 3M corporate, St. Paul, USA) was employed to secure the sensor mats to the residual limb before the silicone liners were rolled on the transducers (Figure 6).



Figure 6. The sensor arrays mounted on the subject's residual limb.

Prior to the experiments, the transducers were calibrated to eliminate variation between each load cell. Following the manufacturer's instructions, two processes of equilibration and calibration were performed. The sensors were inserted individually into a pressure bladder connected to an air compressor and a constant pressure of 100kPa (20psi) was applied for equilibration. Next, the calibration was accomplished according to each subject's body weight. In order to identify the gait cycle, force plate data was simultaneously gathered alongside the pressure data using two Kistler force plates at 50Hz. The subjects walked at a self-selected speed on a 10-meter walkway. Prior to the data collection, the participants practiced the procedure. The frequency of data acquisition was 50Hz. The subjects completed five trials on the walkway. The average of the middle steps (excluding the two first and the two last) for the five trials was chosen for the analyses.

The analyses of data for four sensor arrays (three regions for each) were performed for the three suspension systems. First, the data was normalized to 100 percent of gait cycle. Repeated Measure Analysis of Variance showed significant differences between the studied systems in some of the sensor sites during one gait cycle. Table 3 represents the average peak pressure values and the significant differences observed. There were also significant differences evident between the four sensor sites for each system. In the case of the magnetic lock, there was significant increase in the mean peak pressure at the anterior surface in comparison to the posterior, medial and lateral (79.26 vs. 26.01, 38.07, and 27.41 respectively). The same was true for the pin/lock and Seal-In systems (Table 3).

Table 3. Average peak pressure (kPa) for whole sensor sites at anterior, posterior, medial and lateral residual limb.

Suspension type	Ant	Pos	Med	Lat
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Pin/lock <sup>1</sup>	89.89 (26.4)	47.22 (17.7)	39.21 (18.1)	31.65 (15.2)
New magnetic lock <sup>2</sup>	79.26 (23.2)	26.01 (13.3)	38.07 (12.5)	27.41 (9.8)
Seal-in liner <sup>3</sup>	119.43 (30.8)	65.29 (16.6)	53.50 (21.7)	52.55 (14.5)
Sig. (two tailed)*	1.2 (0.042)	1.2 (0.003)	1.3 (0.034)	1.3 (0.023)
	1.3 (0.017)	1.3 (0.011)	2.3 (0.027)	2.3 (0.015)
	2.3 (0.026)	2.3 (0.000)		

Ant=Anterior; Pos=Posterior; Med=Medial; Lat=Lateral.

\* "1,2", "1,3" and "2,3" indicate that significant differences ( $P < 0.05$ ) were found between each two suspension systems based on the paired-samples t tests.

For the Seal-In liner, the mean peak pressures (APP) were higher in the proximal and middle of the sensor compared to the distal region at the anterior, posterior and medial surfaces of the residuum. Overall, the APP of the four sensor array sites during one gait cycle was higher for the Seal-In system compared to both the pin/lock liner and the new magnetic system. The whole surface APP at the anterior aspect was lower with the magnetic system than it was with the pin/lock system during one gait cycle (79.26 vs. 89.89 kPa,  $P = 0.034$ ,  $t = 2.581$ ). There was also increased APP with the pin/lock system at the posterior aspect of the residual limb during gait cycle (47.22 vs. 26.01 kPa,  $P = 0.000$ ,  $t = 9.254$ ). Comparative analysis of the pin/lock system to the new magnetic system revealed that there was no significant difference between the two during the stance. Nevertheless, significantly less mean peak pressures were seen with the new system during the swing phase of gait (Table 4). Overall, the highest percentage of change was recorded for the posterior sensor between the new magnetic lock and Seal-In system (60.16%) and the least was between the pin/lock and new magnetic lock at the medial surface (2.90%). When comparing the new magnetic lock with the pin/lock system, the percentage of change for all four sensor sites was more than 10%, with the exception of the medial site.

With regards to the distribution of pressure over the anterior surface, the largest change was seen immediately after heel strike for the pin/lock and Seal-In systems during one gait cycle. Conversely, the largest change was observed at late stance with the new magnetic system (Figure 7). As for the posterior surface, a more homogenous pattern was seen for all the suspension systems during gait, with the greatest change at early stance (Figure 7). All over stance, the average peak pressure at the distal region of the anterior surface remained higher than the proximal portion for all three suspension types (Figure 8). The distal area of the posterior surface demonstrated lower pressure than the proximal region. The only exception was the Seal-In system, which produced higher pressure at the middle region in comparison to the proximal area.

Table 4. Average peak pressures (kPa) based on the liner type and sensor sites during the swing phase of gait.

Suspension type	Ant			Pos			Med			Lat		
	P	M	D	P	M	D	P	M	D	M	D	
Pinlock <sup>1</sup>	21.74	10.07	20.03	24.77	11.06	17.74	14.03	15.77	13.24	13.77	14.23	10.12
	(7.3)	(2.4)	(7.8)	(9.6)	(3.2)	(7.1)	(4.9)	(5.7)	(6.3)	(2.2)	(4.0)	(2.1)
Magnetic lock <sup>2</sup>	9.65	10.01	9.74	9.53	9.83	9.92	11.20	10.96	11.68	11.07	11.47	10.14
	(3.5)	(4.9)	(5.7)	(1.1)	(3.4)	(2.5)	(4.2)	(4.7)	(3.1)	(4.8)	(3.7)	(3.6)
Seal-in <sup>3</sup>	72.26	74.2	76.2	40.19	44.80	45.30	30.13	32.51	31.53	34.37	32.50	31.40
	(25.1)	(17.6)	(22.3)	(10.0)	(15.6)	(18.4)	(9.1)	(12.7)	(6.5)	(10.2)	(9.1)	(7.7)
Sig. (two tailed) <sup>4</sup>	1.2	1.3	1.2	1.2	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
	(0.032)	(0.000)	(0.024)	(0.008)	(0.000)	(0.000)	(0.034)	(0.013)	(0.003)	(0.004)	(0.006)	(0.001)
	1.3	2.3	1.3	1.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3
	(0.001)	(0.000)	(0.003)	(0.000)	(0.000)	(0.000)	(0.012)	(0.005)	(0.003)	(0.011)	(0.005)	(0.000)
	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3
	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)

Ant=Anterior; Pos=Posterior; Med=Medial; Lat=Lateral; P=Proximal; M=Middle; D=Distal.

\* "1,2", "1,3" and "2,3" indicate that significant differences ( $P < 0.05$ ) were found between each two suspension systems based on the paired-samples t tests.

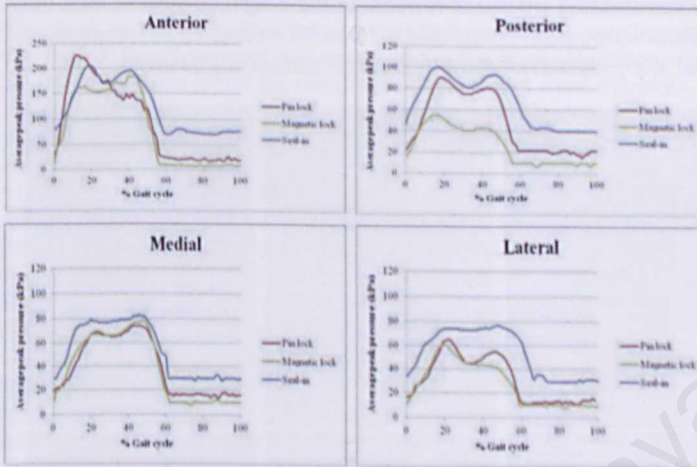


Figure 7. Pattern of pressure acceptance over four sensor sites with three suspension systems during one gait cycle.

When each suspension type was individually evaluated, the pressure was almost distributed evenly at the posterior, medial and lateral surfaces. Nevertheless, the anterior surface accepted the highest pressure magnitudes of all the four limb surfaces (Table 4). The average pressure magnitudes during one gait cycle were less than 200 kPa that mirrored the findings of previous studies that had assessed total surface bearing systems [31,32].

### 2.2.4 Locking Suspension System

Different suspension systems suspend the prosthetic leg by applying pressure at dissimilar regions of the residual limb. This might significantly affect the comfort with which the amputees ambulate. Users of the pin/lock liners feel a stretch at the distal tissue of the residual limb during the swing phase [30]. At the same time, proximal tissues are exposed to high compressive pressures that will disrupt the normal fluid flow. This milking phenomenon can lead to edema and vein problems and could be the reason why pin/lock users experience skin thickening and color change, particularly at the distal region of their residuum [30]. The current study hypothesized that the new system would reduce the traction by increasing the contact area. When the results of each sensor sub region (proximal, middle, and distal) were compared between the two systems, significant differences were evident for the anterior and posterior surfaces of the residual limb (Table 4). Lower peak pressures were produced at the anterior and posterior surfaces during the swing phase of gait with the magnetic system in comparison to the pin/lock. This was in agreement with the findings by Beil and Street (2004) [30], pertaining to high average pressure with the pin/lock system. The average peak pressures at the medial and lateral sensor sites



(mean of whole surface) were also lower with the magnetic system than they were with the pin/lock suspension (10.33 and 9.75 vs. 16.41 and 13.83, respectively). Yet, the statistical analyses did not show them to be statistically different.



Figure 8. Pressure profile with new magnetic lock (top) and pin/lock systems (bottom) during stance; right to left: early stance, mid stance, late stance. All values (average peak pressure) are in kPa.

### 2.2.5 Seal-In Suspension System

The average pressure magnitudes recorded with the Seal-In system were different from the magnetic system during swing (Table 4). A study by Beil and Street (2004) [30] showed that the use of a suction system resulted in a more homogenous distribution of interface pressure. The current study supports their results as the pressure distribution with the pin/lock was less homogenous compared to the new magnetic lock and Seal-In systems. As compared to the magnetic system, the pressure with the Seal-In liner was mainly concentrated at the middle and distal region of the posterior sensor during stance. This might be due to the location of seals and the fact that suction is developed mainly at the distal end where the valve is located. The mean peak pressures were generally higher with the Seal-In liner than they were with the other two systems (P values were less than 0.05 for both comparisons). This was compatible with the results of Ali et al. [33]. In the current study, the pressure values increased by 34.75% at the posterior aspect of the limb with the Seal-In liner in comparison to the pin/lock system. This difference was 40.97% for the new suspension system. The greatest change of pressure with TSB sockets and pin/lock liners in transtibial gait have been shown to occur at late stance (50% of gait cycle) [31].

It was a challenge to compare the results of the current study with the existing literature, as the majority of previous studies used single-spot transducers as opposed to the full-length sensors that were used in this study. Variation in geometry of residual limb could also affect the pressure measurement sites; therefore, a bigger sample size might find a relationship between the residual limb geometry and pressure profile. It is also worth investigating the pressure profile in various activities on diverse walking surfaces. Further investigations may also find association between pressure and pistoning within the prosthetic socket which can be invaluable in the design of a more balanced socket. The current study provided some biomechanical insight into different methods of prosthetic suspension. The new magnetic suspension system might reduce the pressure over the residual limb, particularly during swing, to offer the advantages of the other suspension systems while overcoming some of their weaknesses.

### **2.3 Practical application**

The outcome of this research is a new prosthetic suspension system for individuals with lower limb amputation. The results of the study suggest that the system has the potential to successfully suspend lower limb prosthesis. The new magnetic suspension system might reduce the pressure over the residual limb, particularly during swing, offering the advantages of the other suspension systems while overcoming some of their weaknesses. Therefore, it can be alternatively used for the majority of lower limb prosthesis users.

### **3.0 Commercialization**

BioApps Sdn Bhd is a UM spin-company under the Centre for Applied Biomechanics, Faculty of Engineering, University Malaya. The founders, Prof. Ir. Dr. Wan Abu Bakar bin Wan Abas and Prof. Ir. Dr. Noor Azuan bin Abu Osman had established the company on 17 May 2012.

Bioapps Sdn Bhd provides prosthetic and orthotics services, combining a personal service tailored to specific individual needs with the most advance products and manufacturing techniques available today. Through the Centre for Applied of Biomechanics (CAB), BioApps adopts "From Research to Retail" tagline (Figure 9), commercializing the research outcomes and proactive in establishing quality R&D in the area of P&O. Our research has won various international awards, including the world prestigious Forchheimer Prize in 2013 which is the only award given for P&O research by the International Society of Prosthetics and Orthotics (ISPO) based on their contribution to the community at large. The award was firstly won outside the US and Europe. Over the time, the P&O research results have been published into more than 50 international ISI articles including the Nature Scientific Report. Researchers under CAB have produced a number of products of P&O patents that had been licensed to multi-national companies.

Since January 2015, BioApps actively operates at the Ground Floor, South Tower, University of Malaya Medical Centre (UMMC) and become the only prosthetic and orthotic services distributor for the Department of Rehabilitation Medicine of UMMC. BioApps comprises of one Certified Prosthetist/Orthotist as the Technical Head and 5 Prosthetist/Orthotist staff which graduated from UM P&O degree program. The company's operation is managed by a General Manager with support

from 5 administrative staff. In 2015, BioApps recorded a total of RM 1.3 million sales with 27% net profit. From the sales amount, approximately RM 380,000 has been contributed back to UM as part of BioApps's responsibility as a UM spin-off company. BioApps Sdn Bhd recently has been awarded with Good Distribution Practice For Medical Devices (GDPMD) certificate which demonstrate BioApps's ability to maintain safety and performance requirements specified for the supply of medical. With this certification, BioApps is strategizing to expand its business across all over Malaysia.



Figure 9 Company Logo for Bioapps Sdn Bhd

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