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DEPARTMENT OF HEALTH TECHNOLOGY AND INFORMATICS

Development and Evaluation of Economical Trans-tibial Prosthesis for Rural Area

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A thesis submitted in partial fulfillment of the requirements for the Degree of

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CERTIFICATE OF ORIGINALITY

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ABSTRACT

The mainstream of prosthetic research develops prostheses with cutting-edge technologies. However, only few people can afford luxurious products and most of amputees especially in rural area do not even receive foundational prosthetic service. Some researchers persist in developing economical prosthetic solution. Previous studies suggested the sand casting method (SCM) originated from dilatancy casting principle. It provided an effective casting method without conventional plaster. By combining thermoplastic vacuum forming technique, it was claimed that tans-tibial monolithic prosthesis (monolimb) could be custom-made for individuals in a single-day visit. However, previous clinical trial found that the monolimb made by SCM were loose. The method was further discouraged since monolimb is non-adjustable after fabrication. Previous studies tried to determine the height and alignment of monolimb for individual during the sand casting procedures. Nevertheless, the outcome was not desirable as dynamic alignment could not be determined during the casting process. Our pilot study found air leakage problem of SCM and the auxiliary belt-suspension system of monolimb were other disadvantages.

The objective of present study is to deliver a clinically practical, reliable and economical method to facilitate trans-tibial prosthetic service in rural countries by improving previous technology. Latex membrane was used instead of original plastic bag to enhance endurance and reliability. Latex balloon donned on residual limb was then wrapped by bandage to reduce its girth end hence increased socket fit. It was evaluated by comparing girths of residual limbs and models made with plastic bag coating (condition 1) as well as latex balloon

coating wrapping with bandage (condition 2) in six cases, the girths of models made in condition 1 were significantly larger than that of residual limbs, whereas there was no significant dimensional difference between residual limbs and models made in condition 2. The succeeding monolimbs also reflected that the bandage wrapping technique solved the loose socket problem. A pair of pads was introduced to SCM in order to make indentations over femoral supracondylar regions. The resultant temporary socket was suspended by self suspension mechanism rather than depending on auxiliary suspension system. Traditional prosthetic components were incorporated with SCM to form a temporary prosthesis for length and alignment assessments. Finally, the thermoplastic vacuum forming process was modified to cooperate with the improved SCM. Field test was conducted in a prosthesis center in Shaoguan. Six monolimbs were fabricated for daily use over a year. The casting model was modified to deal with long residual limbs experienced in the test. The system was subsequently introduced to a prosthesis research center in Beijing to collect comment from professionals. The thermoplastic vacuum forming process was modified to adopt conventional prosthetic ankle joint so that the ankle joint of succeeding monolimb was adjustable. In summary, the present study provides a reliable and economical method of monolimb fabrication within few working hours.

Further studies include mechanical test of monolimb with conventional adaptor and performance comparisons between monolimb and conventional prosthesis.

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CHAPTER 1 INTRODUCTION

1.1 Research Problems

Modern prosthetic research aims to provide high-end products with new technology. Computer-aided design systems were introduced to the residual limb casting procedures. Latest prostheses integrate robotic technology to actively control the prosthetic joint in real time rather than passively controlled by the body movement (Marks et al., 2001). However, the investment of developing cutting edge prostheses is extremely high, and its selling-price is only affordable by small portion of people. In reality, many amputees especially in rural countries cannot even afford conventional prosthesis. For this reason, some researchers keep investigating on how to reduce the cost of prostheses (Wu et al., 2004-2009, Lin et al., 2000 and Beck et al., 2001). Dilatancy principle, or vacuum forming, was introduced to residual limb casting procedure (Meads et al., 1949) to reduce the cost and experience for prosthetic socket fabrication. To reduce the cost of trans-tibial (TT) prosthesis, a thermoplastic prosthesis, or called monolimb, has been proposed for more than 30 years (Wilson et al, 1976). Some studies attempted to combine the inexpensive casting and prosthesis forming technique in order to provide an economical scheme to populate the prosthetic service in the rural area (Wu et al., 2004-2009). However, previous studies (Jensen et al., 2005 and 2009) indicated that sockets made according to the dilatancy principle were loose. Moreover, monolimbs were frequently poorly aligned since adjustment was not possible (Vecchiotti et al.,

2004). As a result, it is not until now to successfully formulate a complete process to practically deliver low-cost TT prostheses. The objective of current study is to suggest a clinically practical method to delivery economical trans-tibial prosthesis according to preceding dilatancy casting and monolimb fabrication method.

1.2 Thesis Outline

The aim of this thesis is to deliver a clinically practical, reliable and economical method so that prosthetic service can be populated in rural areas. It is achieved by improving the casting procedures based on dilatancy principle and method for monolimb manufacture. Instead of specific equipment and components, most of the equipment of the casting procedures and prosthetic components are ordinary and reusable. The resin laminated prosthetic socket, metallic proximal adaptor and pylon employed in conventional prosthesis are simply substituted by a piece of thermoplastic in monolimb, and hence the component cost should be considerably reduced. Moreover, in conventional prosthetic fabrication, a good fit custom-made prosthetic socket requires rich experience in plaster model rectification. The presenting study introduces the bandaging method and appropriated shape of socket model should be consequentially formed according to the shape and mechanical property of residual limb. The training course and fabrication time are expected to be reduced significantly. In brief, the current study proposed a low cost alternative method in order that good functioning custom-made TT prostheses can be made with limited resources.

Chapter 2 covers the background of TT amputation, conventional casting method and prosthesis for TT residual limb. Alternative economical prosthetic solutions suggested in previous studies are summarized.

Chapter 3 provides suggestions to solve the problems raised in previous studies such as using alternative coating material and introducing alternative approach for thermoplastic vacuum forming procedures. The succeeding prosthetic manufacture method is introduced in rural area for feedbacks and further improvement.

Chapter 4 presents results of suggested solution in chapter 3. Further improvement is achieved by advices collected in the field test. Finally, an affordable, practical and reliable TT prosthesis manufacture scheme is presented.

Chapter 5 explains how the modifications presented in this study improve the existing techniques so that a fit, well aligned and durable alternative TT prosthesis can be finished with limit resources.

Finally, Chapter 6 presents the conclusions of the current techniques and suggestions for future work.

CHAPTER 2 LITERATURE REVIEW

2.1 TT Amputation

In general, TT amputation means removal of leg across the tibia bone. It should declare the TT amputation in this study means the end of residual limb is taper in shape rather than bulbous shaped and weight tolerable Syme amputation.

2.1.1 Cause

There are over a million new cases of lower limb amputations in the world every year and the rate of amputation was rising (Renzi et al., 2006). The causes of amputations changed geographically (Wrobel et al., 2001). In developed countries such as United Kingdom, there were about 5000 new major amputations a year and the main cause was diabetic mellitus (DM), which reduced the elasticity of blood vessels and hence reduced the blood supply to the foot. The function of peripheral nervous system and immunological response are also impaired by the alternated osmotic potential, hence common skin damage of DM foot is often not awarded until server complaints such as serious inflammation or even ulceration are resulted. About 25% of problematic DM feet were unretrievable and TT amputation was the option to save the life (Chaturvedi et al., 2001, Jeffcoate et al., 2003-2004). The prime reasons of amputation in developing countries are caused by trauma related to conflict. It is estimated that over 1200 victims were harmed by stepping on post-war explosives, such as landmine and unexploded ordnance, every month in the world and most of them had to receive TT amputation (The LEA Study Group, 1995). Globally, although the

main cause of lower limb amputation was diabetic related disease rather than trauma, amputees in rural area were young (Bharara et al., 2009). It is because the onset of DM is about 60 year old, whereas age-independent traumatic injuries were the main cause of lower limb amputations in developing countries (Canavan et al., 2007). It impulses developing countries demand more recourses for life-long prosthetic service.

2.1.2 Surgical Operation

There are several alternative approaches, such as circular skin and fishmouth incision operation procedure, available for TT amputation. However, the most common amputation procedure called long or total posterior flap technique has been shown to be the most effective configuration in patients with lower extremity ischemia (Tisi and Callam, 2004). The amputation level is commonly around the middle of leg (Figure 2.1 a) so that anterior tissues including periosteum and fascia are retained in the anterior cut section and a long posterior myofasciocutaneous flap can be made. The fascia and tendinous portion of the gastrocnemius-soleus group to the periosteum and fascia at the anterior tibia line (Figure 2.2 b). As a result, the bone ends of tibia and fibula are covered by muscle for cushioning. It is generally accepted that preservation of muscle, especially it is not dissected from the crural fascia or skin, will enhance healing of an amputation residual. Continuous myofascial closure over the cut bone end should also prevent adherence of the skin scar to the bone (Figure 2.3 c). While attempting to encompass the involved tissue and maximize the available blood supply, moderate long residual limb is desirable for prosthetic

fitting and stability in ambulation. A length of 7 to 8 inches below the knee joint is ideal (Burgess, 1988).

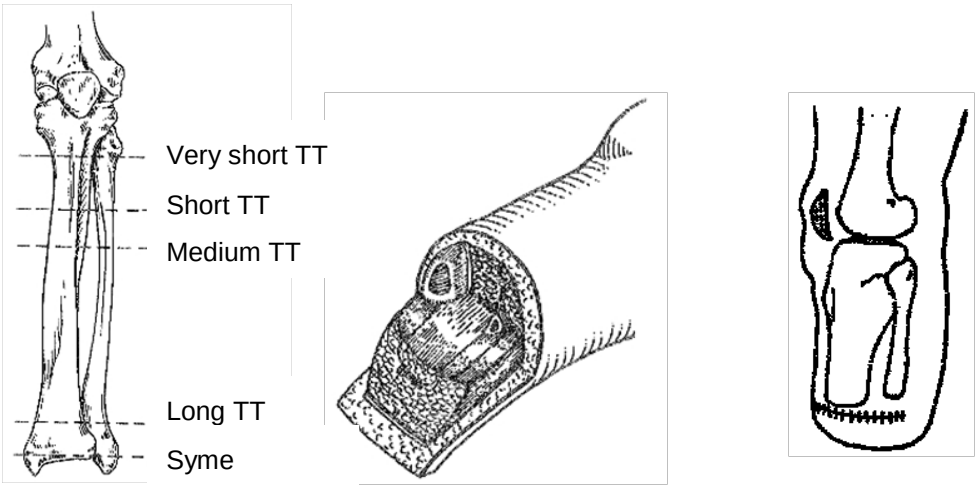


Figure 2.1 TT amputation (a) Amputation levels (b) Posterior skin flap approach (c) Side-view of residual limb

2.2 Conventional TT Prosthesis

TT prosthesis consists of four basic parts including socket, a foot-ankle assembly, a pylon and a suspension system. The success of the TT prosthesis depends largely on the socket fit since it provides an interface to accommodate and support the residual limb during standing and ambulation. Generally, the socket includes a soft interface, called liner, between the residual limb and socket for cushioning. The shape of socket is modified according to the residual limb. There are crests and indentations on the socket to relief and applied pressure over bony prominent and force tolerable regions of the residual limb respectively. Contradictory, alternative hard socket consists no cushioning material and the socket shape is identical to that of residual limb without pressure relief or reinforcement. However, the total contact approach is suitable for round residual limb with bony prominent regions well covered and protected by soft tissue. Soft tissues of residual

limbs are generally not thick enough to protect the sensitive regions from pressure. Socket with soft liner and modification is prescribed in most cases. Below the socket is a connection unit called shank, which connects the socket and the ankle-foot assemble. Apart from transferring load from socket to the ground, the shank maintains the position of ankle-foot assemble relative to the socket. This spatial relationship is known as prosthetic alignment which must be adjusted carefully according to postures of individual amputee during standing and walking. The class of shank determines the types of prosthesis: For the endoskeletal prosthesis, the shank is generally a hollow aluminum pylon connecting to the socket and foot with prosthesis connectors, whereas the shank in exoskeletal prosthesis composed of urethane foam and lamination wall. Endoskeletal prosthesis is more common and preferable since the height and the prosthetic alignment are adjustable after the prosthesis is made. In fact, endoskeletal prosthesis would be focused in this thesis. The foot-ankle unit is the base of the prosthesis which supports the prosthesis as well as the body. Conventional prosthetic foot, such as SACH foot, for TT prosthesis apparently does not have a movable part, but it is deformable and can be compressed and rebounded during walking and provides shock absorption and energy storing units for the prosthesis. The prosthetic foot is off-the-shelf which does not have to be custom-made. The suspension unit holds the whole prosthesis on the residual limb in position. Usually, it is located on the proximal region of the socket, connecting to the thigh or just above the knee region. Some of the suspension units attach to the prosthesis and can be removed and renewed separately. They are called auxiliary suspensions, such as sleeve and belt. On the other hand, some kinds of the suspension units integrated with

prosthetic socket and known as intrinsic suspension type. Supracondylar self-suspension and silicon liner with locking mechanisms are some of the examples. Notwithstanding the types of prostheses, it is expected that the life expectancy of prosthesis is five years in general. However, some prosthetic components may wear out and should be renewed more often. And more importantly, shrinkage of residual limb is a normal phenomena and it is especially dominant for new amputees. Once the residual limb shrinks, the socket becomes loose and it should be remade according to the new residual limb shape.

2.2.1 Traditional Casting Method

This section reviews the conventional plaster casting procedures of TT residual limb for prosthetic socket fabrication.

2.2.1.1 Socket Design

Suspension type should be considered before casting because the shape of model determines the suspension method. Some Intrinsic suspension methods, such as supracondylar self suspension, hold the prosthesis by locking on the supracondylar of the knee, and the trim lime of the socket opening is above the supracondylar regions in both medial and lateral sides, whereas the sockets with auxiliary suspension are identical that the opening of socket do not located above the knee. The casting process for most common supracondylar TT socket is described in this theme since it includes all the techniques required for casting for other types of socket.

2.2.1.2 Negative Model Casting Procedures

The lengths and girths of residual limb are first recorded by referring anatomical landmarks. The distance from mid-patella level to the distal end regarded as the length of residual limb while the girths are measured along different intervals of the residual limb. The width between medial-lateral supracondylar is recorded by prosthetic caliper. After measurement, residual limb is marked with indelible pencil over bony prominent regions such as tibial tubercle, distal end of residual limb, crest and borders of tibia head and neck and end of fibula. Crosses ‘x’ may be marked on the apexes of the prominent regions to identity plaster adding regions for pressure relief. Force tolerable regions such as mid-patella tendon, posterior popliteal, supracondylar region and medial flare of tibia are also outlined with indelible pencil to indicate plaster reduction area for socket indentation. A thin sock is put on the residual limb and the knee is kept in about 15 degrees flexion. One to two rolls of plaster bandage are dipped in water and wrap the residual limb circumferentially from mid-patella level to distal end direction using moderate pressure. Before the plaster bandage is hardened, hold the residual limb with both hands so that the patella tendon and popliteal tissues are compressed by thumbs and fingers respectively. It outlines the depths of soft tissue in the force tolerant area. After the plaster set, dip a roll of plaster in water and wrapped on the residual limb above the supracondylar region of knee by 5cm to distal direction so that the second bandage is overlapping and margined to the hardened plaster. Press the medial and lateral knee supracondylar regions to get the contour until the plaster is hardened. Remove the cast by loosening proximal tissue and flexing the knee.

2.2.1.3 Positive Model Casting Procedures

Plaster is filled into the plaster negative cast, or impression and a mandrel, usually a metal pipe, is inserted in the center. The mandrel should be immersed at least 15cm deep to the plaster and 10cm protrude above the plaster so as to build in the plaster model firmly. After about half hour, tear off the plaster bandage from the model after the plaster has been hardened. The landmarks marked on the residual limb should be transferred to the impression and finally marked on the model. The mandrel is fixed on a clamp for rectification.

2.2.1.4 Positive Model Rectification

Socket indentations are achieved by the concave shape of the plaster model to concentrates pressure on the force tolerant area of residual limb for suspension. The most important indentation areas are regions of patella tendon, posterior popliteal and medial and lateral supracondylar areas. Since those areas are manually pressed with hands while taking the negative cast, the indentation shapes of model are fundamentally achieved. Rectify those regions and measure the depths until they match the record. Plaster on medial flare of tibia region is also removed by about 2 to 3 mm. Regarding to the bony prominent area such as fibular head and tibial crest, 2 to 3 mm of plaster is added to those areas for pressure relieves. Rectify the plaster model until the girths match the measurement. A plaster brim is added above the posterior popliteal with about 12mm in thickness. Finally, extend the length of model by adding 1 to 2cm of plaster over the distal end to avoid weight bearing on the end of residual limb.

2.2.2 Soft Liner

The next step is to make the soft liner on the residual limb model. The detailed procedures would not be described in this thesis. In brief, the liner is usually custom made of a polyethylene sheet, called pelite linear, fabricated with the socket fabrication to provide cushioning effect. Similar to other types of prosthetic liners, it is not washable and can only be cleaned by rubbing with wet cloth. The life-span of a pelite liner is around few years. After the liner is worn out, prosthetists generally prefer to make a new prosthetic socket since it is difficult to mold a liner from a fabricated socket with conventional casting material.

2.2.3 Lamination

The lamination process is not described in deep in this thesis. In brief, the procedures required at least three pieces of specified PVA bags, about 500ml of lamination resin depending on the size of residual limb, small amount of chemical as catalyze for curing the resin, perlon, glass or carbon fiber for strengthening the socket. Whatever the prosthesis is of exo- or endoskeleton, prosthesis should conduct 2 times of lamination process, and each lamination procedure spends at least 45 minute for hardening. Vacuum pump is required during the lamination process. After the second lamination is over, plaster cutter is used to cut the socket along the trim line. Remove all the plaster inside the socket by hammering the mandrel. It may be a time consuming process depending on the rigidity of plaster and the size of socket. Sanding machines are often used to polish the edges of sockets for better finishing. It should be caution that the non-biodegradable particles, such as

lamination resin, glass fiber and carbon fiber, emitted in the finishing procedure are harmful for prolonged inhalation.

2.2.4 Alignment

Fabricated socket is ready to connect with the prosthetic connectors, pylon and prosthetic foot to form the TT prosthesis. Amputee first puts on the prosthesis and stand to adjust static alignment. Prosthetist observes the alignment of TT prosthesis with respect to the posture of amputee in both sagittal and coronal planes. Leg length discrepancy is corrected by using a suitable length pylon. Tilting angles of the proximal and distal prosthetic adaptors on the pylon should be adjusted until the pylon is vertical and the knee is neither in hyper-extension nor hyper-flexion. After the static alignment is completed, the amputee may walk with the prosthesis for dynamic alignment adjustment. Dorsi/Plantar-flexion and toe in/out angles may be adjusted upon the ambulation performance.

2.2.5 Suspension Methods

There are several suspension approaches for TT prosthesis, prosthetists prescribes suitable suspension method according to the residual limb and financial conditions of patients. Collectively, common TT prosthesis suspension approaches employed usually included: prosthetic sleeves, silicon liners with locking mechanisms, supracondylar cuff suspension and supracondylar self-suspension systems (Grevsten, 1978).

2.2.5.1 Prosthetic Sleeves

Suspension sleeve is an elastic tube usually made of synthetic impermeable material such as latex, rubber or neoprene materials. The sleeve is rolled over the proximal portion of socket and extended for about 10cm above the knee. As a result, the top of socket is sealed by the impervious membrane and the prosthesis is hold by negative pressure. The friction between socket and sleeve also contribute to suspension force. Since the suspension system requires simple technique, it is used widely in some rural areas. However, the synthetic material is vulnerable to crack and it is expected to be replaced regularly. The air-tight and directly skin-contacting features of the sleeve can also cause perspiration and hygiene problems (Lake et al., 1997), it is necessary to keep the residual limbs clean especially for whom living in hot or humid environment. Moreover, the knee joint motion is restricted.

2.2.5.2 Silicon Liner with Locking Mechanisms

As same as the principle of the prosthetic sleeve, the suspension force of this type of TT prosthesis is maintained by negative pressure within the socket and friction. Additionally, the silicon liner with a locking pin located on the distal end provides both cushion and suspension function at the same time. The silicon liner is first turned over and rolled directly onto the residual limb in order to capsulate the residual limb with impervious liner without air tracked. The liner is then connected and locked by an adaptor located in the socket so that the whole prosthesis can hung on the residual limb. Since the suction force is maintained by the liner surrounding the residual limb rather than embracing the knee joint in the case of sleeve suspension, the movement of the knee joint is not restricted. Although the liner with locking approach

provides reliable suspension, skin problem may be elicited by the impervious membrane. Furthermore, the high cost is only affordable in developed countries. The life-span of silicon liner is around 2 years.

2.2.5.3 Supracondylar Cuff Suspension

The supracondylar suspension cuff is a leather strap embracing the knee joint to prevent the belt from slipping off the proximal patella. It attaches to the medial and lateral proximal regions of the prosthetic socket on the suprapatellar level. It is one of the most common suspension methods for TT prosthesis since it offers an affordable and simple method to hold the prosthesis on the residual limb. However, the belt suspension approach is rarely used nowadays as the range of knee flexion is restricted and skin damage may be resulted by rubbing. And more importantly, atrophy of soft tissues is often caused by the clutching force of the belt.

2.2.5.4 Supracondylar Self-Suspension

This type of prosthetic socket grasps and holds the residual limb by the indentation shape over supracondylar region of the knee. The simple design eliminates additional components for suspension to reduce the cost. Similar socket structure with higher anterior wall is often prescribed to those with shorter residual limbs in order to provide additional surface area for weight bearing and improve knee stability. However, it requires experience and higher technique to fulfill the task since the distance between the medial and lateral wedge is critical. If the gap is too wide, there will not be enough grasping force for suspension, otherwise it is difficult to put on and off the prosthesis and may cause discomfort.

2.3 Low Cost Prosthetic Service (For Developing Countries)

The overall cost of a conventional TT prosthesis is relatively high in developing countries. For instance, although plaster used as casting material is at low cost, its heavy and non-reusable natures increase the transportation cost; the casting and rectification procedures require time and experience such that the cost of training a prosthetist is considerable. The components of TT prosthesis, such as lamination resin, pelite sheets and PVC bags, are specific, non-reusable and costly as well. For these reasons, prosthetic service is professional and rarely available in hospitals for small towns or remote area. Amputees in distant area may spend days to visit prosthetic clinics. In addition, the life-span of TT prosthesis last only for few years in general, depending on the speed of residual limb shrinkage and deterioration of prosthetic components. Ultimately, it is common to find broken and custom-made prostheses in rural area. For improvement, it is recommended the casting and socket forming procedures should be simplified to reduce the time, material cost, demand of experience and professionals. It may be achieved by casting with dilatancy principle and prescribing monolithic prosthesis.

2.3.1 Monolithic Prosthesis (Monolimb)

As the name implies, monolithic prosthesis, or simply called monolimb, comprises of a piece of material rather than assembled with different parts in convention prostheses (Pages 9-13). This section reviews monolimb and potential applications for low cost prosthesis service.

2.3.1.1 History of Monolimb

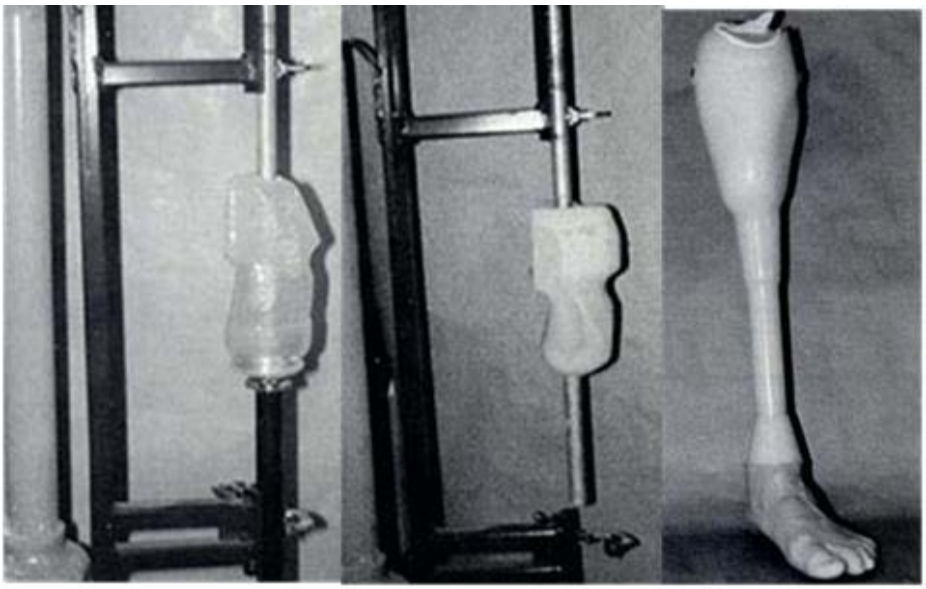
Monolimb was developed in 1970s (Wollstein, 1972). It refers to TT prosthesis which both the socket and shank are made of one piece of thermoplastics (Figure 2.2 a). By attaching a conventional prosthetic foot on the distal end of monolimb through a monolimb adaptor or foot bolt (Figure 2.2 b), lightweight TT prosthesis is finished. It was originally proposed the monolimb was made according to conventional endoskeleton TT prosthesis, or called check prosthesis (Figure 2.2 c), so that proper socket shape and alignment can be confirmed. The laminated socket may be replaced by a thermoplastic vacuum forming check socket to simplify the fabrication procedures.

a b c

Figure 2.2 Monolimb (a) Fabricated monolimb (b) Foot bolt (c) Temporary prosthesis

The ankle joint of check prosthesis is restricted to title in any direction since the monolimb adaptor can only be perpendicularly connected to prosthetic foot. Tilting angle of the pylon in the proximal connector is adjusted instead until acceptable static and dynamic alignments are obtained. The monolimb adaptor of temporary prosthesis is then fixed on an alignment jig duplicating

jig which inserts a mandrel in the socket cavity (Figure 2.3a). Plaster is then filled into the cavity so that the socket model is formed and held in an exact alignment. The check socket, distal adaptor and pylon are removed, whereas proximal adaptor connecting on the alignment jig is replaced by a monolimb adaptor and a cylinder-shaped pylon dummy (Figure 2.3b). A piece of polypropylene is soften by heat and draped over the entire set for thermoplastic vacuum forming. After the thermoplastic is cooled and hardened, excessive plastic are trimmed alone the boundary of TT prosthesis and the plaster model and pylon dummy are removed. The monolimb is completed after a conventional prosthetic foot is connected to the monolimb adaptor (Figure 2.3c). Although the pylon and prosthetic connectors are retained and reusable, the plaster, socket (either made of resin or thermoplastic) and time consumed in the fabrication procedures make the monolimb expensive and not preferable clinically.

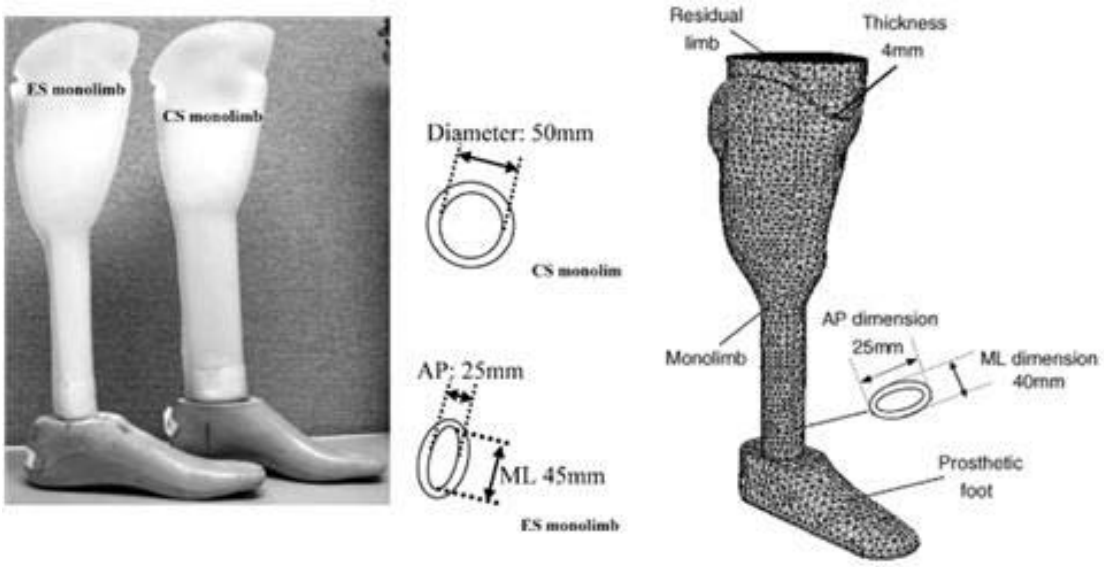


a b c

Figure 2.3 Monolimb Alignment duplicated from temporary prosthesis (a) Temporary prosthesis fixed on alignment jig (b) Plaster model of impression with removal of prosthetic components (c) Monolimb made from thermoplastic vacuum forming procedures.

2.3.1.2 Advantages of Monolimb

Apart from the light weight and simplicity of monolimb, previous researchers believe monolimb offers additional benefit. The pylon of monolimb made with flexible thermoplastic provides an energy storing function in ambulation (Beck et al., 2001). At heel strike, the pylon will bow slightly anteriorly, thus simulating plantar flexion of the foot. Conversely, during midstance and push off, the thermoplastic pylon will bow posteriorly, simulating the dorsiflexion angle required for effective push off. Valenti (1991) recruited 46 patients tried the monolimb who initially used the conventional TT prosthesis. About 80% of them claimed the monolimb provided greater flexibility, improved gait efficiency and extended ambulatory endurance. Coleman et al. (2001) compared ground reaction forces of four unilateral TT amputees wearing prostheses with interchangeable aluminum (rigid) pylon and nylon (relatively flexible) pylon. He found that during the subjects walking with the flexible pylon, significant earlier vertical loading and later push-off peaks, along with higher maximum anterior-posterior forces were detected compared with using rigid pylon. It suggested that the subjects transferred weight to and from the prosthesis more dynamically. Lee et al. (2004, 2005 and 2006) also suggested monolimb with elliptical shaped pylon provided more flexibility and improved the gait performance compared with monolimb with circular shaped pylon in terms of mechanical test (Figure 2.4a), gait analysis and finite element analysis (Figure 2.4b).

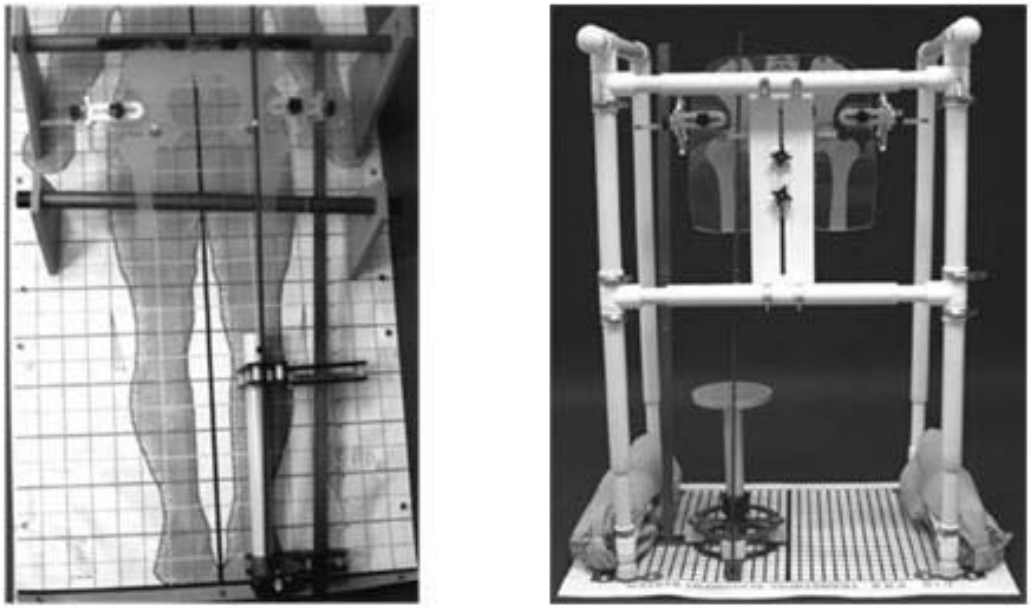


a b

Figure 2.4 Alternative Pylon Shape Analysis (a) Monolimbs with circular and elliptical pylons (b) Computational model of monolimb with elliptical pylon

2.3.1.3 Drawbacks of Monolimb

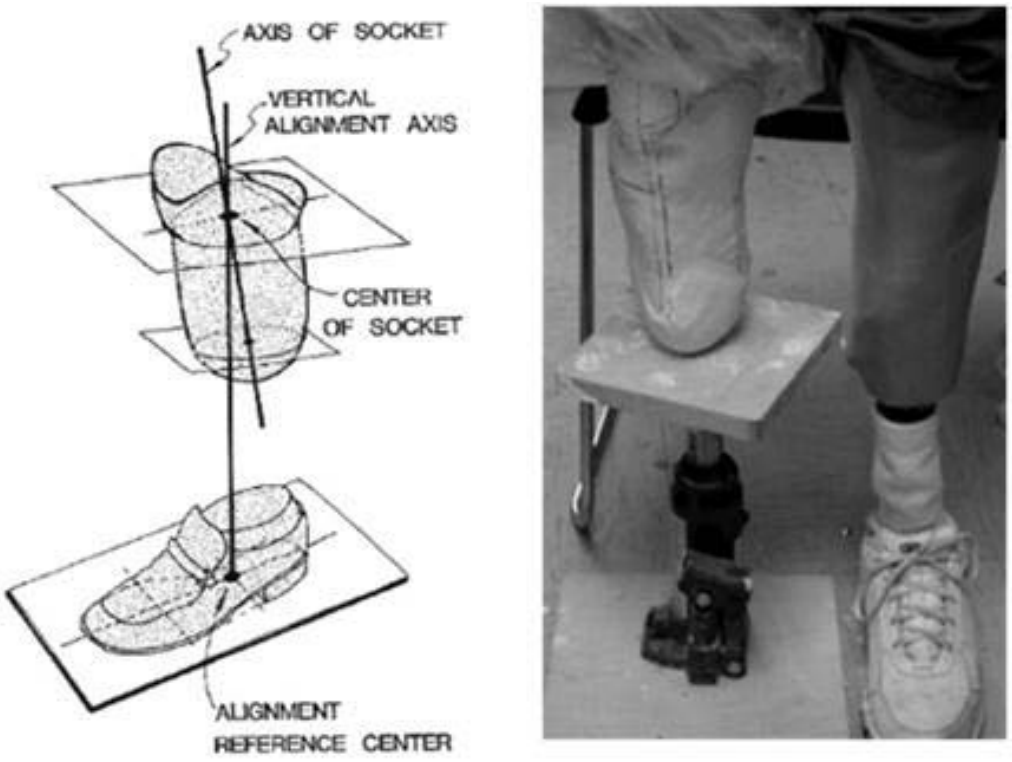
Although the monolimb offered light weight and low material cost (neglecting the cost of manufacture procedure) which conventional prosthesis never commits, the obvious shortcoming is that the monolimb offers no alignment adjustments. As a result, temporary prosthesis should first be made to determine the static and dynamic alignments and followed by complicated alignment transfer procedures as proposed in the original method. Consequently, the increased material and labor cost reduce the clinical value of monolimb. To solve this problem, alternative methods were suggested to determine prosthetic alignment rather than making a temporary prosthesis. Beck et al. (2001) developed an alternative anatomically based-alignment (ABA) theory which determine the position of prosthetic foot bolt by referring anatomical landmarks only (greater trochanter and knee center) either in supine (Figure 2.5a) or standing (Figure 2.5b) position.



a b

Figure 2.5 ABA System for Monolimb (a) supine and (b) standing position

Wu et al. suggested another alternative method called vertical alignment axis (VAA) technique, which is based on the principle that the socket center falls perpendicularly to the alignment reference center on the supporting base (Figure 2.6). Although both methods systemically and rationally predict the prosthetic alignment for individual amputees without temporary prosthesis, they provide no information about dynamic alignment. Vecchiotti et al. (2004) fabricated monolimbs according to the two techniques for five amputees and suggested that problems such as excessive knee flexion and lateral or medial leaning of pylons were observed during the dynamic alignment assessment. It is claimed that modification needed to be incorporated into the alignment systems for improvement.



a b

Figure 2.6 VAA System for Monolimb (a) Depiction of the VAA technique, geometric center of socket is projected vertically to trace location of foot bolt. (b) VAA alignment during weight-shifting maneuvers.

2.3.2 Dilatancy Casting Principle

A flexible impervious bag filled with grainy material will be hardened and resist deformation if the air is evacuated from the bag, this phenomena is known as dilatancy effect. If the air is being sucked out from the bag while it is embracing a solid subject, the impression of the subject will be captured by the hardened bag (Figure 2.7a). It is called dilatancy casting principle. The dilatancy principle was first patented by Mead in 1948 to provide an alternative molding method instead of using conventional casting material such as plaster or wax. Mead also gained a patent in 1949 which claimed a method to take the impression of residual limb by the dilatancy casting

principle. He proposed to use a flexible, impervious bag filled with granules to embrace the residual limb, then harden the bag to form a impression of residual limb by reducing the air pressure inside the bag (Figure 2.7b).

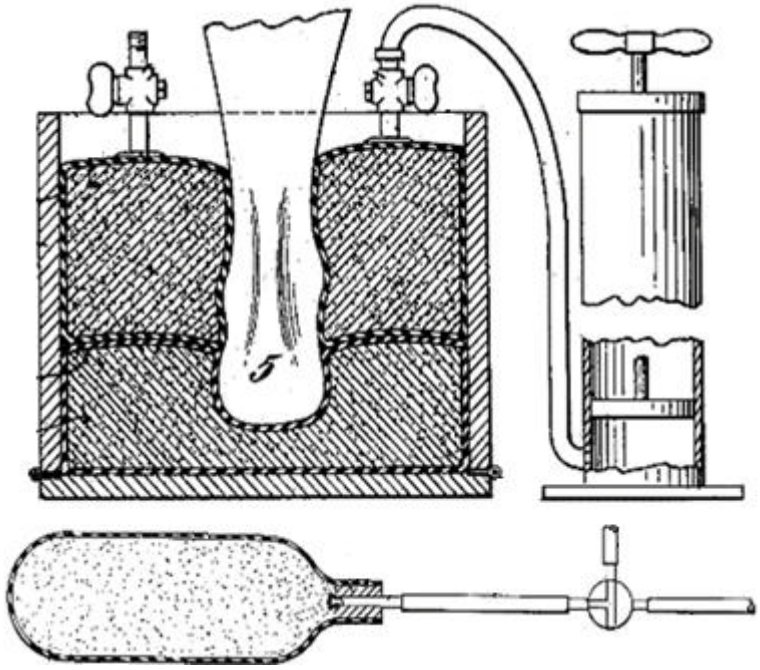
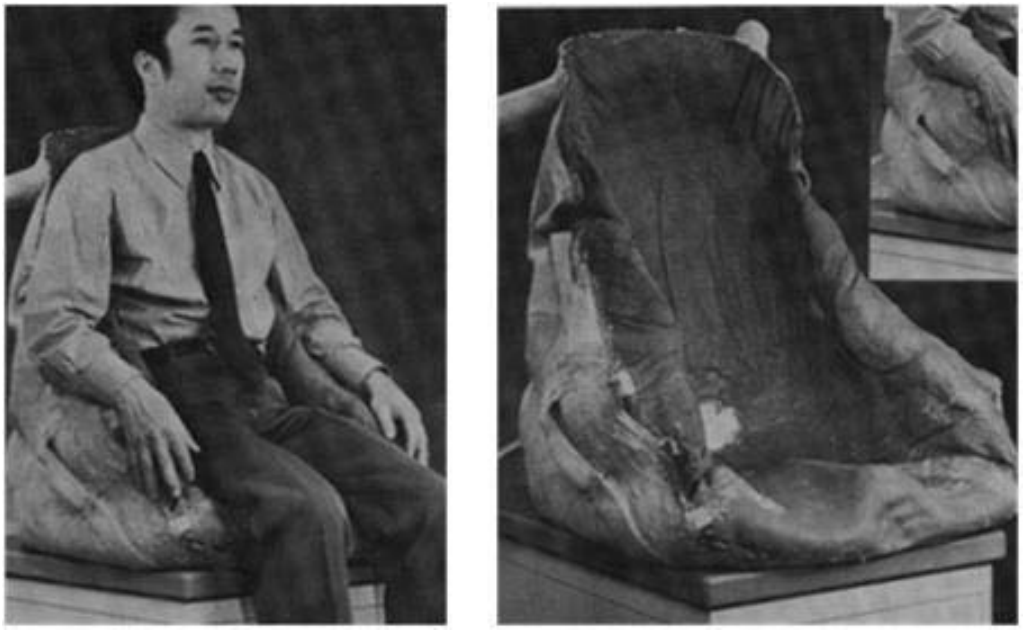


Figure 2.7 Dilatancy Casting Principle (Upper). Human foot impression casting (b) Impervious bag with granules

In orthotics, the technique has been proposed (John et al., 1973, Germans et al., 1975, Ring et al., 1978) to mold special seating impression for provide extra support for the severely disabled for over 30 years. It became a conventional casting method for common seating clinic nowadays (Figure 2.8).



a b

Figure 2.8 Casting for Special Seat Design by Dilatancy Casting Principle (a) Subject seated on an impervious bag filled with granules. (b) The bag hardened by vacuum pressure

2.3.2.1 Sand Casting Method (SCM)

Mead, however, did not suggest the method of taking the positive model from the impression. Until 1994, Wu presented SCM which takes both impression and model of residual limb by dilatancy casting principle. He proposed to use thin plastic (e.g. polyethylene) bag and sand as flexible impervious coating and granules respectively. Bony prominences and pressure sensitive areas, such as tibial crest and fibular head, are first covered by water-based clay or soft padding for pressure relief over the residual limb. Then a plastic bag is put on the residual limb serving as an air-sealing coating. The position of plastic bag is kept by a thin nylon sock. While the residual limb was inserted into a casting container (a tube with one blind-end which connected to vacuum pump) in standing position, fluidized sand is filled into the container 2cm above the femoral condyle (Figure 2.9a). The opening of the container

was then sealed by the plastic bag and a rubber band. After the air was evacuated from the container by vacuum pump, the solid impression of residual limb was formed and the residual limb can be withdrawn from the container (Figure 2.9b). To make the positive model by the same dilatancy casting principle, the impression was filled with sand and a vacuum forming mandrel was placed in the center. The plastic bag from outside of the container was turned over and seal around the vacuum forming mandrel. The model was formed by removing air from the plastic bag via the vacuum forming mandrel (Figure 2.9c). Suction source connects to the casting container is released to normalize the negative pressure in the casting cylinder. The rubber band and the model can be removed from the casting container (Figure 9d). To make indentation on the sand cast model, the author suggested piercing the plastic bag on the indentation sites and temporarily reducing the negative pressure of model so that concave shape can be made by hammering or (Figure 2.10a) pressing with thumb or pipe. After modification, the holes were sealed by sticking adhesive tape to stop air leakage. The model was ready for make the definitive prosthetic socket by either thermoplastic vacuum forming or conventional lamination method (Figure 2.10b). The demolding process was simply achieved by cutting off the negative pressure and pouring out the sand from the socket. It was effortless compared with demoulding conventional plaster cast because no hammering is required (Figure 2.10c). Eliminating the plaster fabrication procedure made the process fast and simple. Besides, excepting a cheap plastic bag, all the casting materials are reusable and the whole process involves only low end equipment. It was claimed the prosthetic socket can be finished within an hour (Figure 2.10d) and it was especially suitable in rural

area. Wu granted his first patent regarding the TT prosthesis fabrication procedure in 2004, which suggested the plastic bag coating of negative models (impression) and positive models (model) might be replaced by latex balloon wrapped with pressurized coating and only latex balloon respectively. However, the procedure and evaluation of the alternative coating approach have not been implemented.

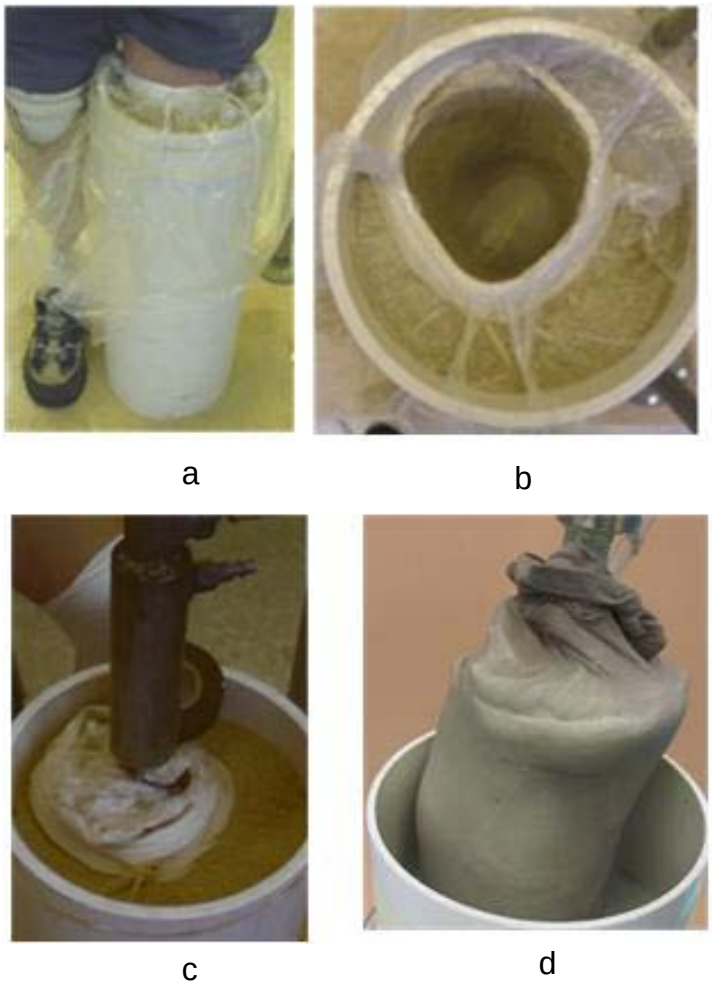
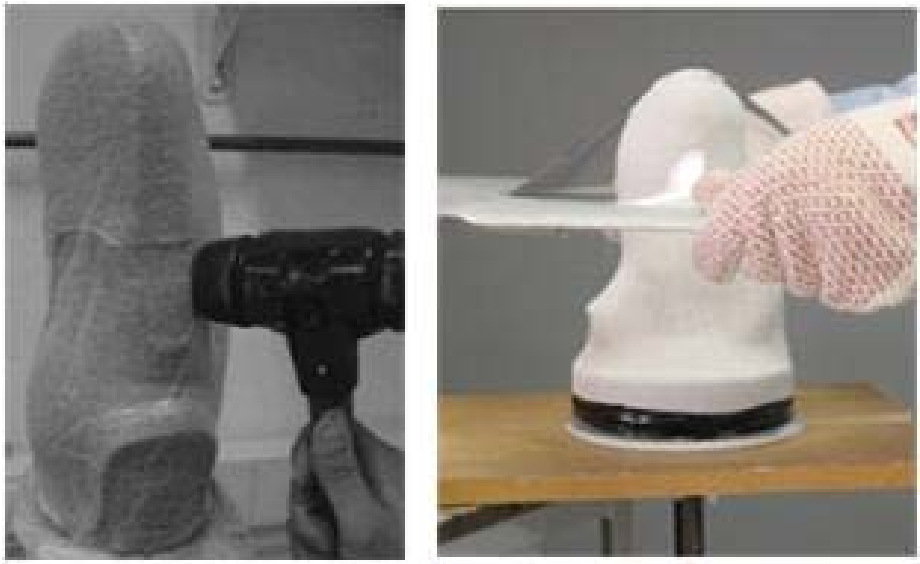


Figure 2.9 Procedures of SCM (a) Residual limb buried in casting cylinder (b) Impression of residual limb (c) Suction mandrel in the center of impression and filled with sand (d) Sand casted residual limb model



a b

c d

Figure 2.10 TT socket moulding from Sand Casted Model (a) Indentations of sand cast model is made by hammering (b) Thermoplastic vacuum forming of sand cast model (c) Demoulding by simply pour the sand out (d) Walking with prosthesis made according to SCM

2.3.2.2 Feedback of SCM

Jensen et al. (2005) fabricated TT prosthetic sockets according to SCM for 28 TT amputees. The sockets were found to be consistently and evenly larger than residual limbs and required to put on two to five socks to fit with. Apart from loose socket issue, plastic bags are not desired to be the air sealing coating in SCM. The plastic bags are usually pierced and caused air leakage during the positive model rectification and the thermoplastic vacuum forming processes. The models might partially deform or even totally destroy.

2.3.2.3 Sand Casting Bag

Until 2007, Wu granted the second patent about the SCM. It was proposed to use soft silicon or other impervious bag filled with small granules, known as casting bag, to replace the original casting cylinder. It eliminated the steps of inserting the residual limb and filling up the granules in the cylinder. Instead, the casting bag was just rolled over and embracing the residual limb (Figure 2.11a), and the bag was hardened by dilatancy principle to become a ‘temporary impression’ of the residual limb (Figure 2.11b). Actually, the idea was identical to Mead’s patent titled ‘method for making impression of objects’ in 1949, but Wu’s patent included the positive model casting procedures with the ‘temporary impression’ by dilatancy casting principle using plastic bag and small granules as described previously (Figure 2.11c and 2.11d). The detail and application of the casting bag was published in 2008, which emphasized on taking the model without plaster in a short time. The model modification was identical to the previous SCM. Although air leakage problem of the impression was solved, that of positive model persists.

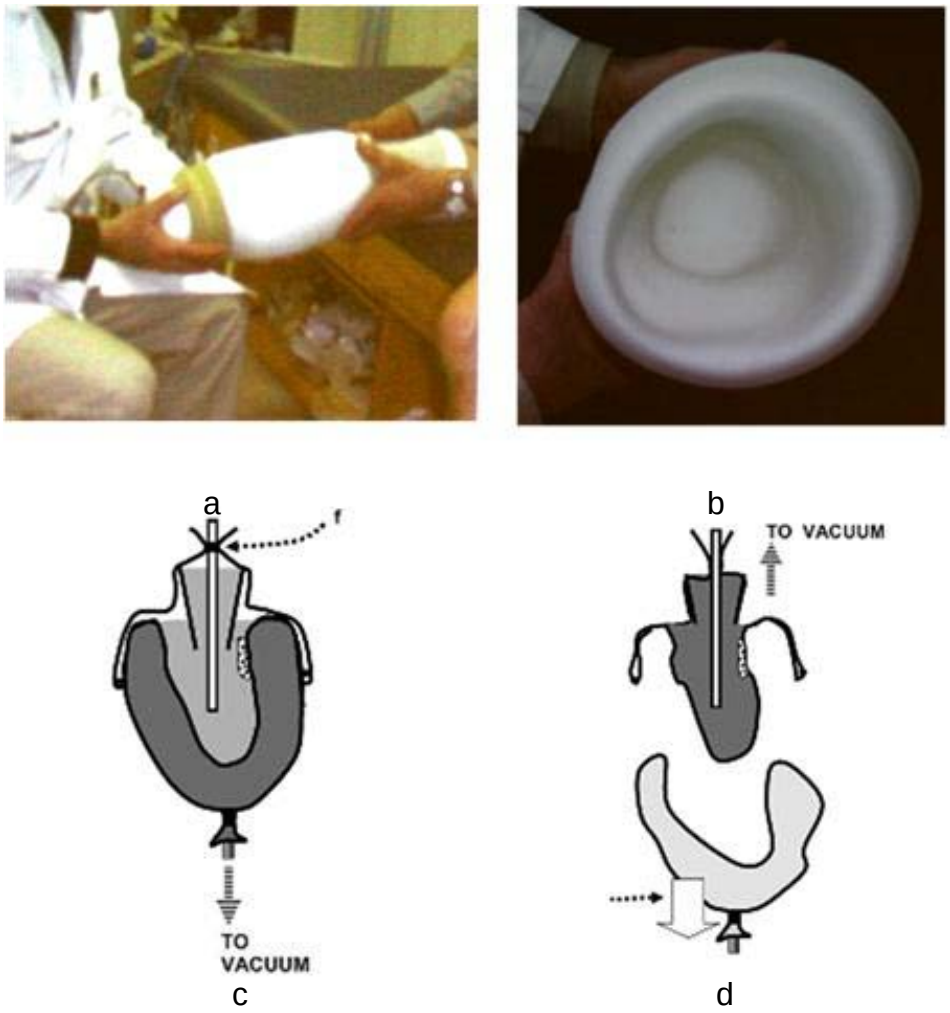


Figure 2.11 Casting Procedures with Casting Bag (a) Rolling the casting bag on Residual limb (b) The bag hardened by negative pressure and become impression (c) Deployment of plastic bag, sands and suction mandrels for modeling with casting bag (d) Vacuum applied via the mandrel to form the model and neutralize the pressure of casting bag for demoulding.

2.3.3 Sand Casting and Alignment System

Wu further modified the casting bag (Patent US 2009 U.S. 2009/0143868 A1*)* so that prosthetic adaptors, pylon and foot were combined with the casting bag to form temporary prosthesis for alignment adjustment (Figure 2.12a). Once the bag rolled over the residual limb and hardened by dilatancy casting principle, a temporary prosthesis was available to determine static and dynamic alignments. The tilting angles of prosthetic connector and length of

pylon were adjusted until the suitable alignments were determined. The foot bolt of temporary prosthesis was then separated from the prosthetic foot and fixed on an alignment jig which projects a mandrel inside the cavity of the impression (Figure 2.12b). The alignments were preserved since both of the model and foot bolt were fixed in the alignment jig. The casting bag and connecting prosthetic components were removed from the alignment jig and a monolimb was ready to be produced by thermoplastic vacuum forming. However, the model was not made with plastic bag and sand according to dilatancy casting principle proposed previously. On the other hand, the inventors suggested forming the model in the casting bag with conventional plaster. The distal end of plaster model was then drilled in coronal and sagittal plans to the form two through holes. Strings pass through the holes of model and connected to foot bolt and form two close loops (Figure 2.12c). After straightening, the strings provide a skeleton for the pylon of monolimb during thermoplastic vacuum forming. It was a simple way to provide a firm connection against the strong contraction force of thermoplastic during vacuum forming process. The methods for model modification were absent in the patent. Instead, the total contact approach of socket design was suggested. Finally, a monolimb with X-shaped pylon was delivered after thermoplastic vacuum forming (Figure 2.12d). Although the last proposed casting method provides a method to have temporary socket for alignments and monolimb making, the disadvantages of using plaster, such as increasing the material cost and time consumption, were re-introduced to the casting process. Moreover, the total contact socket design was only suitable for residual limb protected with thicker soft tissue.

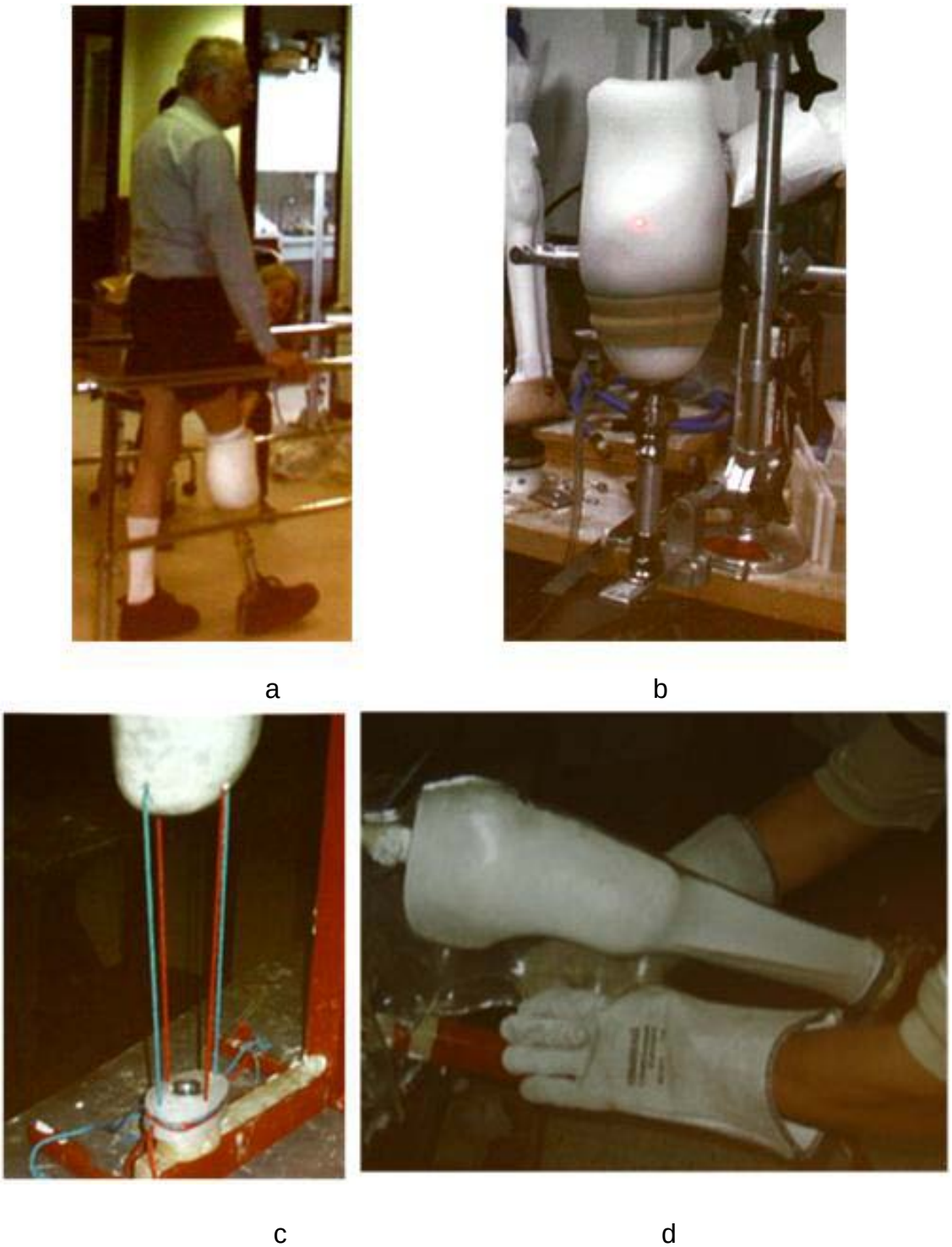


Figure 2.12. Alignment transfer in Wu's sand casting and alignment system (a) Casting bag combines with prosthetic components to form temporary prosthesis (b) Temporary prosthesis is fixed on an alignment jig after tuning, mandrel and plaster filled in the impression (c) Strings passing through the plaster model and foot bolt to serve as a skeleton of pylon (d) Thermoplastic vacuum forming of the model, foot bolt and strings to form a monolimb with X-shaped pylon.

2.4 Summary

From the dilatancy casting principle proposed in 1949 to Wu's sand casting and alignment system suggested in 2009, there are numerous resource spent in economical TT prosthesis development. However, the SCM for socket fabrication never did come to a technical breakthrough in the developing world (Thanh et al., 2009). Impervious coating made with plastic (polyethylene) bags coating often suffer from uncontrollable air leakage since the bags were easily pierced under vacuum pressure. Vacuum pump has to be kept operating in order to maintain the shape and hardness of both impression and models. Our pilot experiments also agreed with Jensen and his colleagues (2005) that sockets made according to original SCM were too loose to fit. Regarding to the casting bag and alignment system, although alignments can be confirmed with temporary prosthesis, the proceeding monolimbs depend on auxiliary suspension systems such as sleeve and belt suspensions. The outcome of total contact socket approach in the last casting and alignment system is also questionable for residual limbs with thin soft tissue in most cases.

CHAPTER 3 METHODOLOGY

3.1 Proposed Solutions

This study suggests improvement through

1. Replacing the plastic bag with a highly elastic material to increase reliability of both impressions and models;
2. Improving the loose socket issue;
3. Introducing the temporary prosthesis with self suspension for alignments and
4. Conducting practical field tests in rural areas for feedback and improvement.

3.2.1 Latex Balloon is used instead of Plastic Bag in SCM

Latex balloon is used instead of plastic bag as air sealing coating (Figure 3.1a). The diameter of a fully inflated balloon can be more than 60cm (Figure 3.1b). The high elasticity provides a perfect coating to prevent air leakage. In addition, the latex coating is inert in high temperature, especially important in vacuum forming procedures since the temperature of thermoplastic moulded on models exceeds 180° C. Ordinary double-sided tape is used as a temporary adhesive to connect stretched latex balloon on casting cylinder with air-sealing feature. The price of latex balloon is $5 Hong Kong dollars, it is relative cheap compared with conventional plaster bandage.

a b

Figure 3.1 Latex balloon used in SCM (a) Latex balloon is used as coating material for both impression and model instead of plastic bag in modified SCM. (b) The diameter of balloon can exceed 60cm after full inflation. The extraordinary elasticity of latex balloon greatly reduces the risk of air leakage.

3.2.2 Improvement of Loose Socket

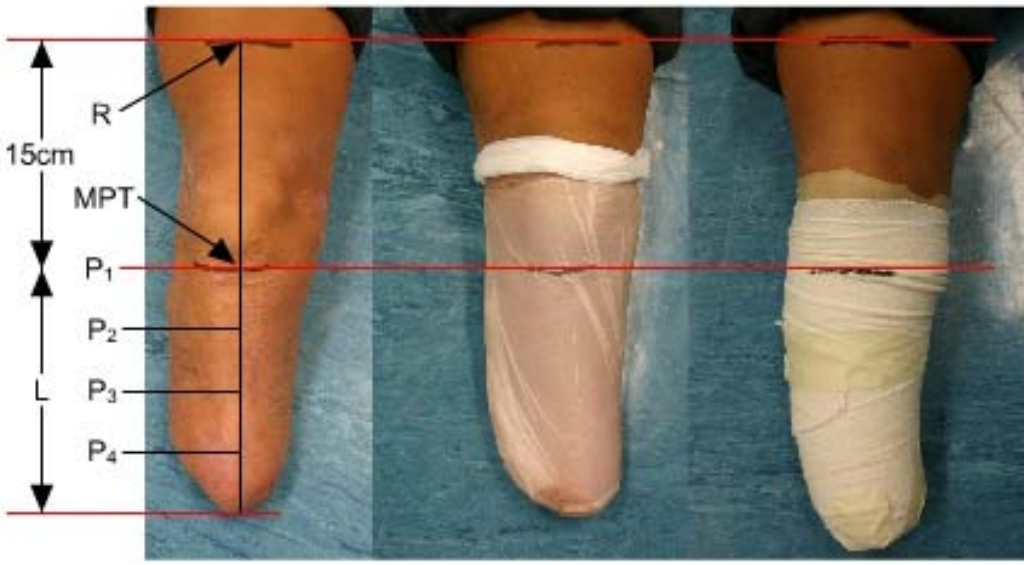
Socket fitness is an important factor to determine the success of the casting method. Wu (2004) suggested putting pressurized coating on impervious coating in the casting procedure, but it was not evaluated. Our pilot study showed that plastic bag coating was too slippery to hold pressurized coating firmly, it was excluded and only latex balloon was used in following experiment. The models of residual limbs were made according to SCM with plastic bag coating (Group 1) and latex balloon wrapped with elastic bandage (Group 2). The lengths and girths of models made from the two conditions were compared to the original dimensions statistically.

3.2.2.1 Subjects

Six unilateral TT amputees were recruited in the experiment. They were walking with conventional TT prostheses with supracondylar suspension prescribed in hospitals for more than 5 years. Details of the experiment were explained to the participants and consent forms were signed by them before the experiment.

3.2.2.2 Original Dimensions of Residual Limbs

Straight lines were marked on the mid-patella tendon (MPT) level and 15cm proximally on the thigh as a reference line (R) as shown in Figure 3.2a. The length (L) from MPT level to the distal end was recorded and regarded as the length of residual limb, which was then evenly divided horizontally into 4 intervals (P1 to P4) and the girths were recorded on each level.



(a) (b) (c)

Figure 3.2 Measurements of residual limb and model made according to original SCM (a) MPT level and reference line(R) were marked, L and girths (P1 to P4) were measured on the residual limb. (b) The mark on the plastic bag is apart from R 15cm in condition 1. (c) The marks on the latex cap and bandage are apart from R 15cm in condition 2.

3.2.2.3 Condition 1: SCM with Plastic Bag Coating

A thin matched-contour plastic bag was put on the residual limb as impression coating. The MPT level was marked on the bag by 15cm distally apart from R (Figure 3.3b). A thin elastic sock was then put on the residual to keep the position of the bag. The residual was inserted into a 'casting cylinder' of which one of the ends was connected to vacuum pump. After the subject was standing well with walking frame in knee extension position, uniform glass beads with 0.85mm in diameter were poured into the cylinder and filled up to MPT level (Figure 3.3a and 3.4a). The plastic bag was pulled over the cylinder for sealing with a rubber band. Vacuum was applied to form a solid impression in few seconds and the residual limb was removed from the cylinder (Figure 3.3b and 3.4b). A suction mandrel was inserted into the cavity of impression and glass beads were filled to make the model (Figure 3.4c). The plastic bag from outside the cylinder was folded upwards onto the mandrel to seal the glass beads and applied vacuum to form the model. Finally, the rubber bend was removed and the model was drawn from the cylinder (Figure 3.3c and 3.4d). L and P1 to P4 of the model were recorded according to the MPT mark drawn on the plastic bag coating.

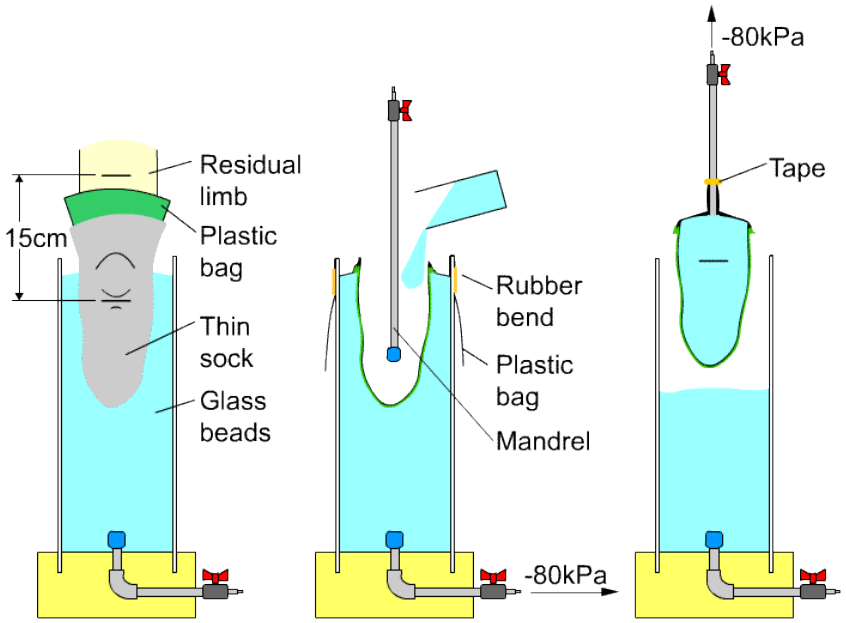


Figure 3.3 Illustration of original SCM

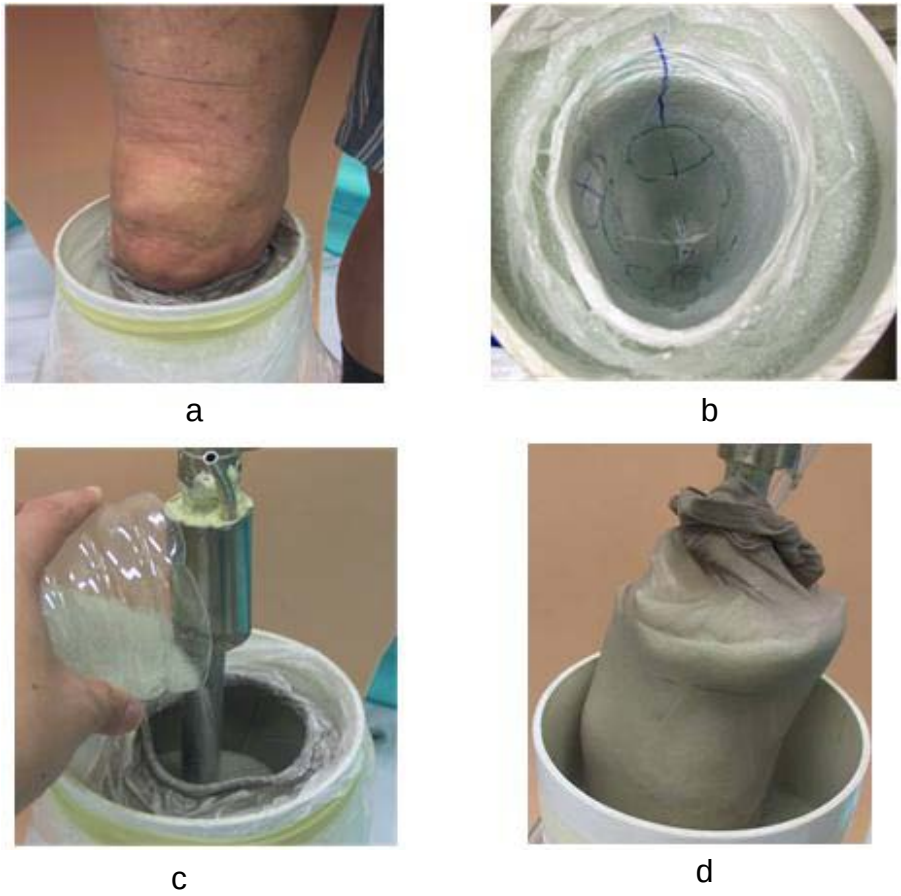


Figure 3.4 Procedures of original SCM. (a) Residual limb with plastic bag coating (condition 1) in casting cylinder, (b) impression of residual limb, (c) impression filled with glass beads and mandrel and (d) the positive model made in condition 1.

3.2.2.4 Condition 2: SCM with Latex Balloon Coating

Latex balloon (Figure 3.1a) with inflated girth over 150cm was used as air-sealing coating. The coating of model was made of a whole balloon, whereas the coating of impression was made of a latex cap which made by trimming the mouth of balloon (Figure 3.5).

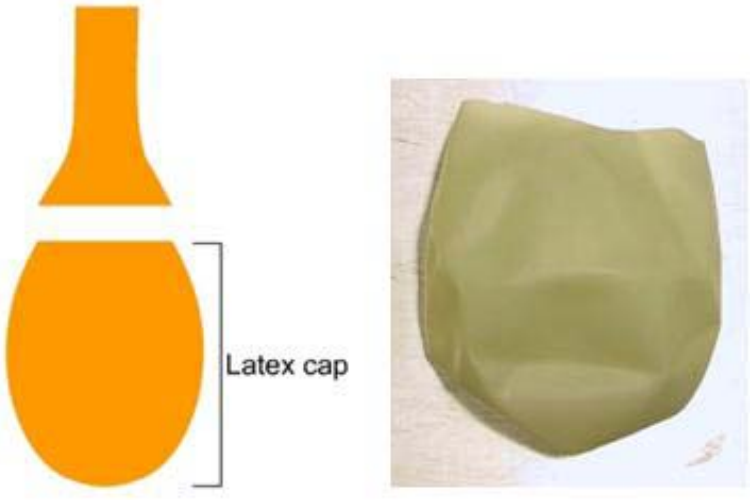
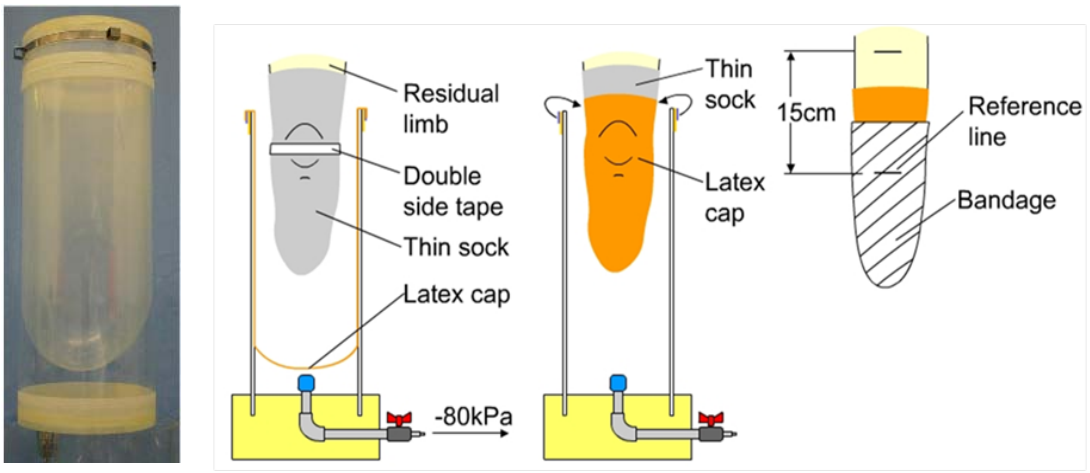


Figure 3.5 Latex cap for SCM used in condition 2

Double sided tape was stuck around the opening of casting cylinder and latex cap was stretched and stuck on it. The cylinder was connected to vacuum source to suck the cap downward until the end of cap almost reached the bottom of the cylinder (Figure 3.6a and 3.11a). A thin sock was put on the residual and double sided tape was stuck around mid patella level. The residual limb was inserted in the cylinder so that the mid patella level was under the opening by about 5cm (Figure 3.6b). Vacuum source was disconnected from the cylinder to let the latex cap retracted upward and wrapped on the residual. The latex cap was detached from the cylinder and stuck on the adhesive tape on the thin sock (Figure 3.6c). The residual limb embraced by latex cap was removed from the cylinder. Bandage was

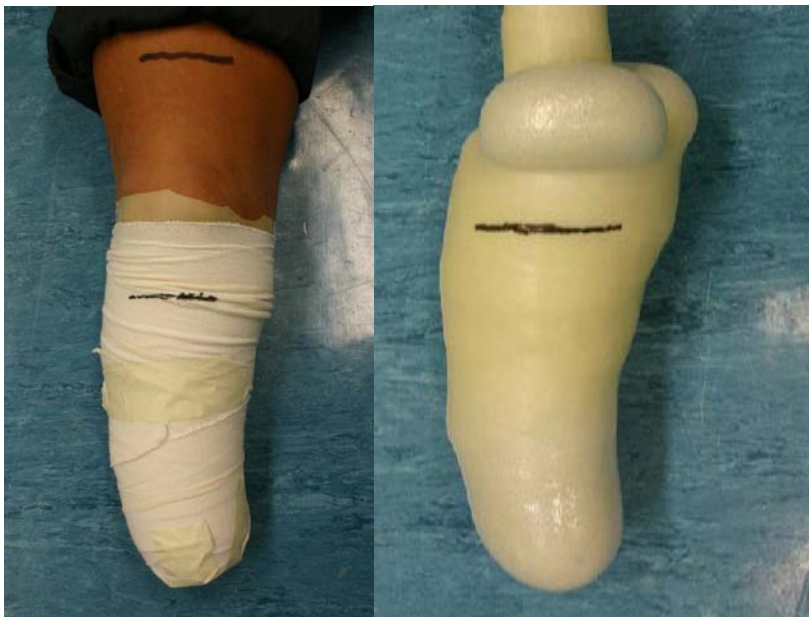
wrapped on the residual limb to squeeze it from proximal to distal direction. The translated MPT line was marked on the bandage distally apart 15cm from R (Figure 3.6d and 3.7a).



a b c d

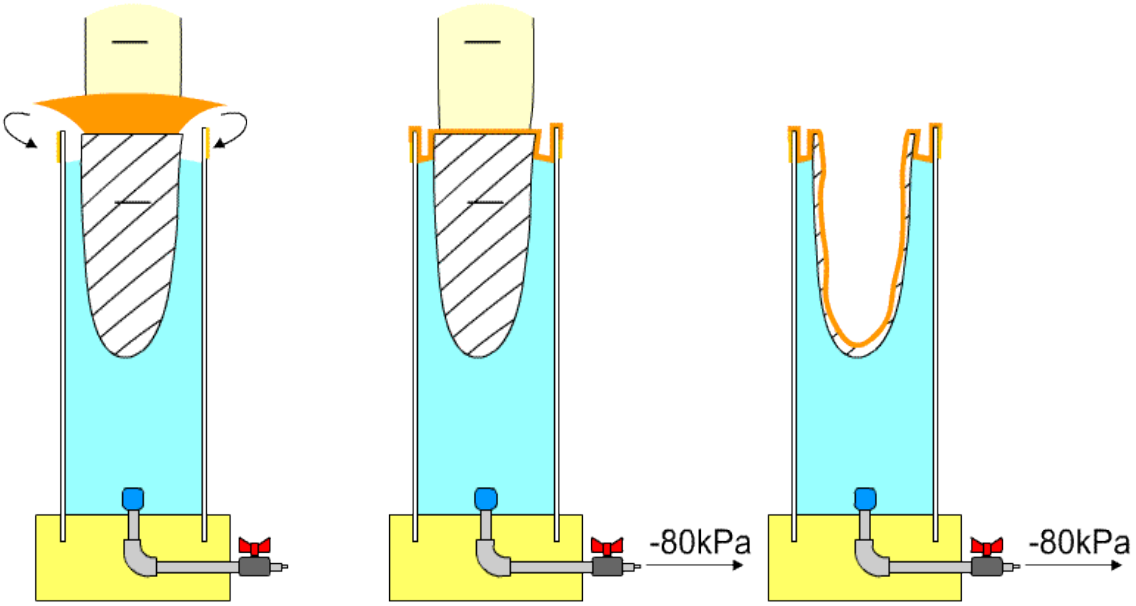
Figure 3.6 Procedures of putting latex cap on residual limb and bandaging

The residual was buried by glass beads in casting cylinder similar to the case in condition 1. The latex cap was folded outward and stuck onto the double side tape around the opening of cylinder (Figure 3.8a). After the subject was standing well, the pressure within casting cylinder was reduced to form the impression (Figure 3.8b) and the residual was withdrawn from it (Figure 3.8c, Figure 3.11b).



(a) (b)

Figure 3.7 Coating of residual limb and model made in condition 2 (a) Residual limb coated with latex balloon and wrapped with elastic bandage. The marks on bandage are marked apart from R by 15cm. (b) Model made with latex balloon coating in condition 2 (Bandage removed).



a b c

Figure 3.8 Impression forming by SCM with latex coating

To make the model with latex coating, the neck of a balloon was stretched outward and wrapped on the mouth of vacuum cap (Figure 3.9a). A thin sock was enveloped over the impression to provide a thin gap for second vacuum. Vacuum cap (Appendix A7) was then placed on the top of cylinder and the gap was air sealed with masking tape. While the pressure in the cylinder was sustained in -80kPa, the pressure within the cavity of impression was reduced to about -40 kPa via air outlet of the cap. The shape and hardness of impression was maintained by pressure difference. While the balloon was being expanding and sucking downward, it was pushed down with a suction mandrel to make it stretch more evenly. After the balloon expanded and completely lied on the impression, the cavity was then filled with glass beads and the original casting mandrel (Appendix A8 without the middle part and funnel) was inserted through the month of the cap (Figure 3.9b and 3.11c). The month of balloon was detached from the cap and wrapped upward onto the mandrel and sealed with PVC tape. Air outlet of mandrel was connected to vacuum source to form the model (Figure 3.9c).

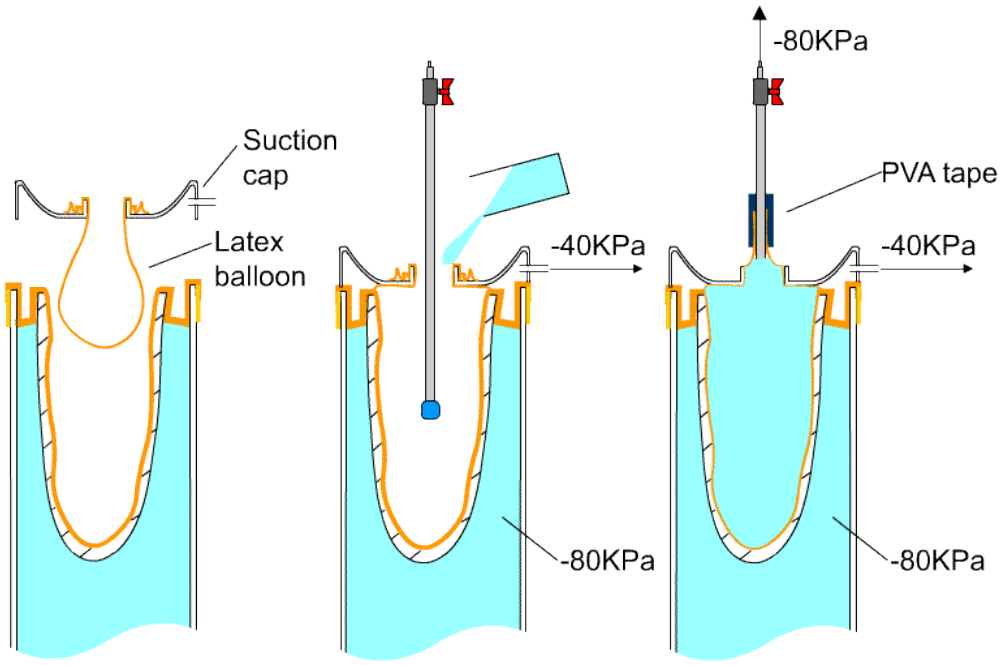


Figure 3.9 Model forming of SCM with latex coating

The cylinder and the cap were dismissed to obtain the model wrapped with bandage. The model was fixed in position by holding the mandrel with a clamp. The position of mark on the bandage was preserved by a laser beam projection (Figure 3.6a, 3.10a and 3.11d). The bandage was removed and a straight line was drawn on the model according to the laser line to get the translated MPT level. The L and P1 to P4 of the model were recorded (Figure 3.7b and 3.10b).

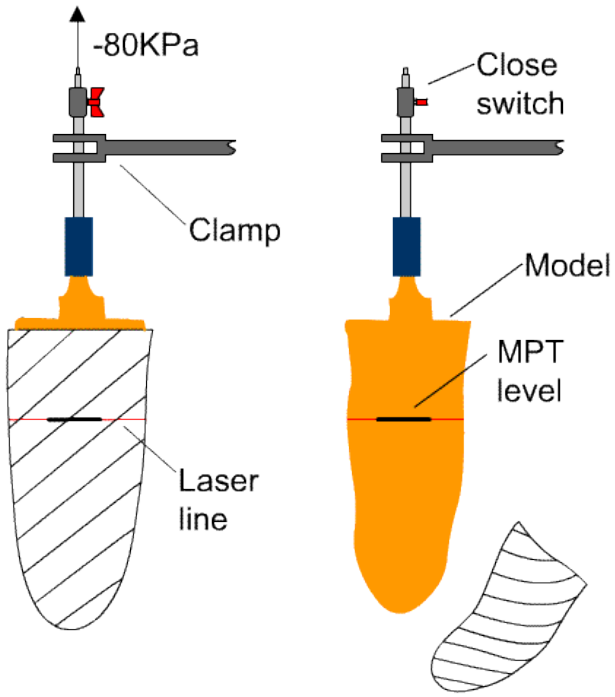


Figure 3.10 MPT mark transfer in condition 2. (a) Model wrapping with bandage in condition 2 is fixed on a jig and a laser beam is projected on the model and overlapping the MPT mark. (b) Remove the bandage and mark the MPT level on the model according to the laser beam.

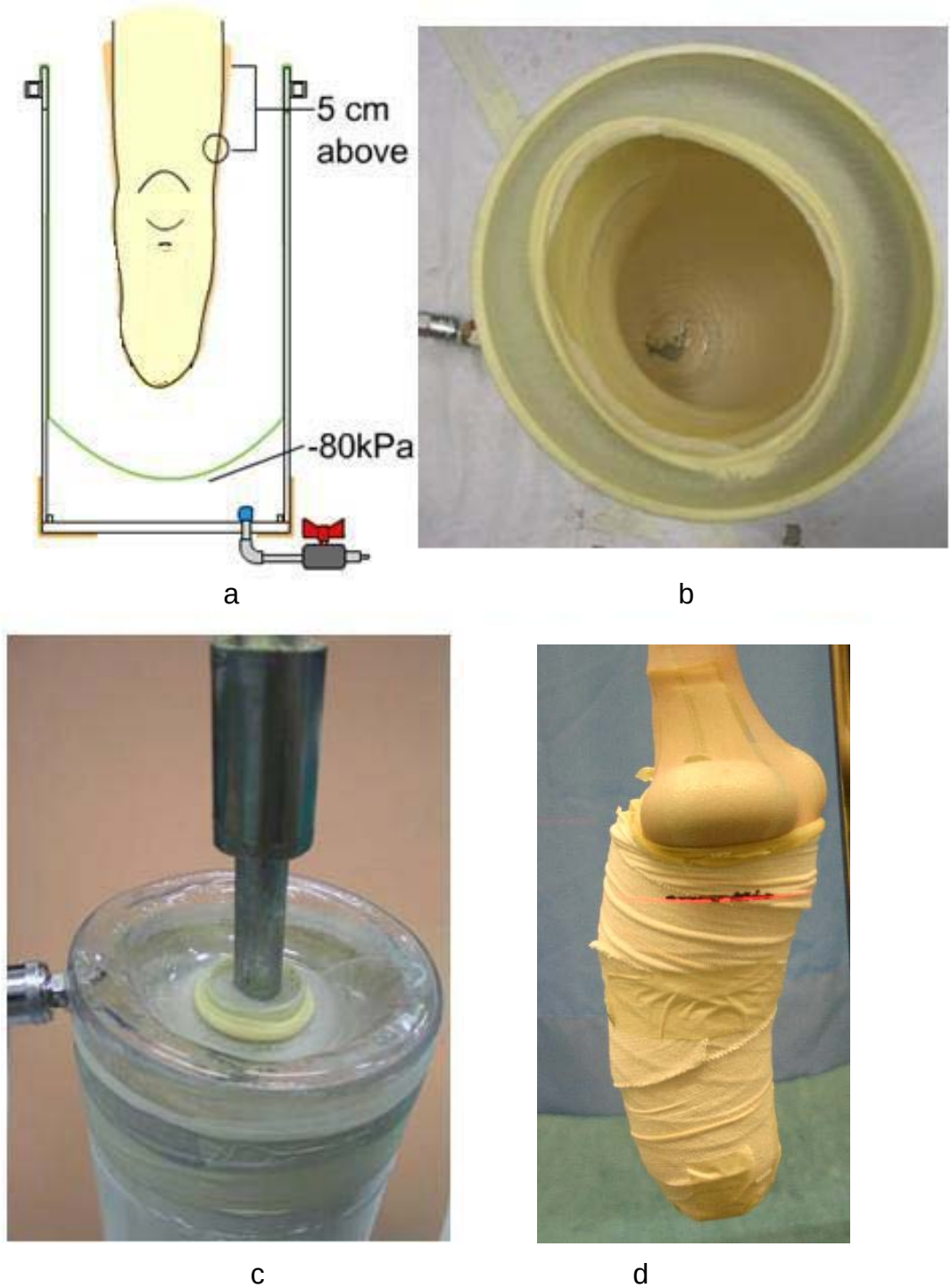
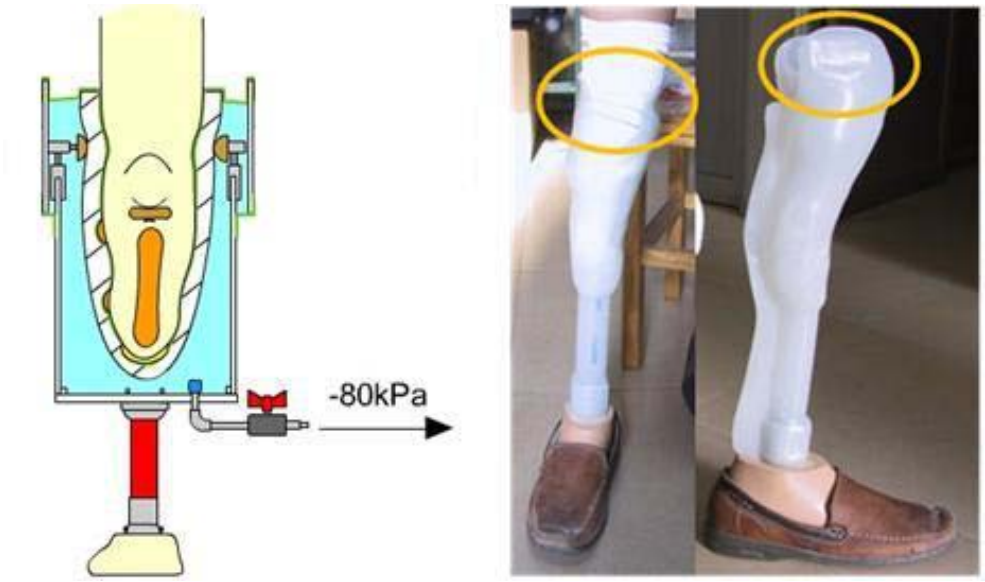


Figure 3.11 Procedures of SCM in condition 2 (a) latex cap was sucked down in a cylinder, (b) impression of residual limb in condition 2, (c) glass beads and mandrel filled into balloon mounted on the vacuum cap to form the positive model and (d) the model removed from the casting cylinder and fixed on a frame. Leaser projected and overlapped the reference line marked on the bandage. A line referencing to original MPT level was marked on the latex balloon according to the laser projection after the bandage is removed.

3.2.3 Temporary Prosthesis with Self Suspension Feature to Determine Alignments

The casting cylinder was re-designed to connect traditional prosthetic components including pylon, adaptors and prosthetic foot to form temporary prosthesis to determine both static and dynamic alignments. In addition, the cylinder was separated into two sections with different diameters. The edge of thinner cylinder reached MPT level where a pair of antennas attached and raised a pair of pads perpendicularly pressed against the supracondylar region of the knee (Appendix A10-13). The protrusions around supracondylar regions are created on resultant impression and eventually provide a pair of knobs for self-suspension of temporary prosthesis and succeeding monolimb (Figure 3.12). The antennas and pads were then embraced by the upper thicker cylinder.



a b

Figure 3.12 Illustration of suspension by supracondylar clamps (a) the pads press against supracondylar region and provide an indentation shape for socket suspension. (b) The indentations of impression were duplicated to the monolimb.

Amputees can stand and walk with the temporary prosthesis for alignment assessment and adjustment (Figure 3.13). After confirmation, temporary prosthesis will be mounted on alignment jig for monolimb fabrication. Both the supracondylar indentations of socket and alignment of the temporary prosthesis will be duplicated to the definitive monolimb.

a b c

Figure 3.13 Alignment of temporary prosthesis (a) standing on the temporary prosthesis for static alignment, (b) walking with the prosthesis for dynamic alignment and (c) alignment of the temporary prosthesis was duplicated to succeeding monolimb.

3.2.4 Field Tests in Developing Country for Improvement

The modified SCM was integrated with thermoplastic vacuum forming method for TT monolimb manufacture. In 2007, the technique was demonstrated in Shaoguan prosthetic service center of China Disabled Persons' Federation. Monolimb was prescribed to six TT amputees for long term use (one year). Inclusion criteria for enrolment included ages 18 to 50, unilateral TT amputation caused by trauma for more than 2 years and current

use of TT prostheses. Exclusion criteria included skin problem on residual limb and secondary health problems such as pulmonary disease and neurologic disorder. The performance of the original TT prostheses for each subject was scored according to Amputee Mobility Predictor (AMP) designed by Robert et al. (2002) as shown in appendix C. The subjects' self-assessed satisfaction with the original prosthesis was assessed with the first question of the PEQ (Prosthesis Evaluation Questionnaire), i.e. 'Over the past four weeks, how happy have you been with your prosthesis?'. Afterwards, the subjects fitted with the monolimb and evaluated by AMP. The monolimbs were prescribed to the subject for voluntary use for one year, and they were asked the first question of PEQ again to evaluate the self-assessed satisfaction of monolimb in long term use. The performance and satisfaction of original and monolimb prostheses were compared by paired T test of the scores of AMP and PEQ respectively. Apart from patient feedback, opinions of casting and fabrication technique from prosthetists were collected for improvement. In 2009, the casting and fabrication methods were improved and performed in China National Research Center for Rehabilitation Technical Aids. Professional prosthetists were participated to provide comment on the casting and fabrication procedures. The instruction was updated and described in appendix B.

CHAPTER 4 RESULTS

4.1 Latex Balloon Is Used As Impervious Coating

The latex balloon provides high elasticity and air sealing feature to replace plastic bag as impervious coating for sand cast method. Instead of elastic rubber band, affordable double side tape was used to securely fix latex membrane on casting cylinder with air sealing feature. The air leakage problem of both impression and model was greatly reduced by using latex balloon as impervious coating instead of plastic bag.

4.2 Dimension Comparison

The lengths and girths of residual limbs and model made in conditions 1 and 2 were recorded and shown in Table 4.1.

Table 4.1 Dimensions of residual limbs in different coating conditions

		Original (cm)	Plastic Bag Coating (cm)	Latex Balloon wrapped by bandage (cm)
Subject 1	Len	16	15.5	15
	MPT	31	32	30.5
	L1	25	27.5	25
	L2	20.5	22	22
	L3	18	20.5	20
Subject 2	Len	17	17	16.5
	MPT	32	34	32.5
	L1	30.5	32	31
	L2	28.7	30.5	29.5
	L3	25.7	28	27
Subject 3	Len	13	13.5	13.5
	MPT	28	30	27.8
	L1	26	27.5	26.8
	L2	25	25.8	24.5
	L3	24	25.5	22.8
Subject 4	Len	13.5	14.6	14.6
	MPT	29	30.5	29.5
	L1	26.3	27.5	27
	L2	25.7	26.8	26
	L3	25	25.8	24.5
Subject 5	Len	17	17.5	16
	MPT	31	31	30
	L1	27	28	27
	L2	24.5	25	24.5
	L3	22	23	23.5
Subject 6	Len	13.2	13.4	14.4
	MPT	31.5	33.5	32
	L1	31	33	31.6
	L2	31	31.5	29.5
	L3	26.8	25.3	25.6

Paired t-test were performed to determine the dimensional differences and summarized in Table I.

Table 4.2 Results of paired t-test and mean dimension difference of residual limb models made with difference casting technique

Parameter	p-value of paired t-test (mean difference)		
	R:Con1	R:Con2	Con1:Con2
L	0.696	1	1
P1	*0.022 (-1.42)	1	*0.001 (1.45)
P2	*0.002 (-1.62)	0.087	*0.029 (1.183)
P3	*0.016 (-1.03)	1	0.062
P4	0.363	1	0.489

*significant ($p \leqq 0.05$); the unit of mean difference is cm

R, Con 1 and Con 2 indicate residual limb, Condition 1 and 2 respectively

'R:Con1' mean residual limb compared to model made in condition 1

The results of paired t-test showed that, with the exception of length and girth on distal level (P4), the girths of models in condition 1 were significantly larger than that of residual limb by 1 to 1.6cm. The models made with plastic bag coating increased in girths from P1 to P3, which explained why Jensen et al. (2005) made loose socket according to SCM. The distal regions (P3 to P4) dimensions of model in condition 2 were not significantly different from that of residual limbs. Furthermore, with respected to the girths in the proximal regions P1 to P2, the models made in condition 2 were significantly thinner than models made with plastic bag coating by 1.18 to 1.45cm. The results indicated that the proximal girths of models made with SCM would be

significantly reduced by using balloon coating and bandage wrapping method.

4.3 Supracondylar Regions was Grasped by a Pair of Pads

Pair of antennas and pads (Appendix A13) was design to provide a low-technology and affordable method to make indentations on the supracondylar regions of both temporary prosthesis and monolimb for self-suspension (Figure 4.1).

a b

Figure 4.1 Supracondylar indentations on temporary socket and monolimb (a) Adjustment of antennas and pads during casting. (b) Supracondylar suspension of proceeding monolimb.

4.4 Field Test in Rural Areas

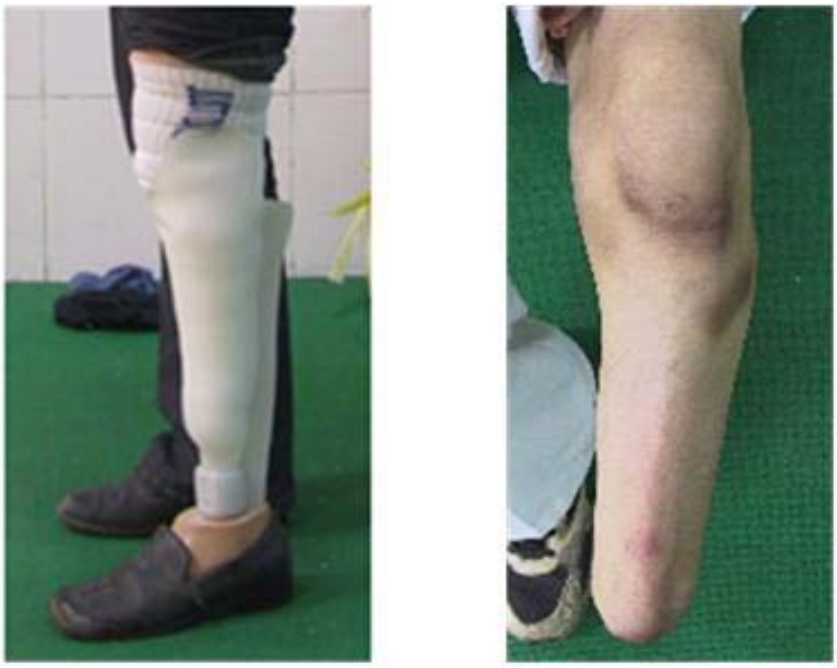
Modified SCM and monolimbs fabrication were demonstrated in China and the technique was improved according to the feedback from the field tests.

4.4.1 Field Test in Shaoguan

The technology and equipment were introduced to the Shaoguan rehabilitation center of China Disabled Persons' Federation in 2007. Six local unilateral trans-tibia amputees were recruited.

4.4.1.1 Opinions of casting and fabrication technique from prosthetists

Monolimbs were custom-made and delivered to them for long term use (Figure 4.2a). After a year, it was reported that the monolimbs were still serving as their daily use prostheses. The material cost of each monolimb was about $200 HK dollars (excluding the conventional prosthetic foot). The casting procedures and monolimb fabrication took about one day. It was proven that the technology provided a fast and affordable method to popularize TT prostheses in the rural areas.



a b

Figure 4.2 Long residual limb in field test (a) Lateral view of residual limb with monolimb in standing position. (b) Residual limbs of amputee are generally long in Mainland.

However, a drawback of the casting method was discovered in the field test: most of cases were unexpectedly classified as very long residual limb and it was not experienced in pilot studies (Figure 2.1a and Figure 4.2b). It caused the latex balloon had to stretch longer to form the coating of models. Unfortunately, the latex balloon was not stretching evenly but concentrated on the tip of balloon. As a result, the latex coating was over-stretching around the tip of models and eventually burst before thermoplastic vacuum forming procedures were completed (Figure 4.3). In brief, sand cast model coated with latex balloon was unreliable for long residual limb. Local prosthetists preferred to use conventional plaster casting method rather than the modified SCM.

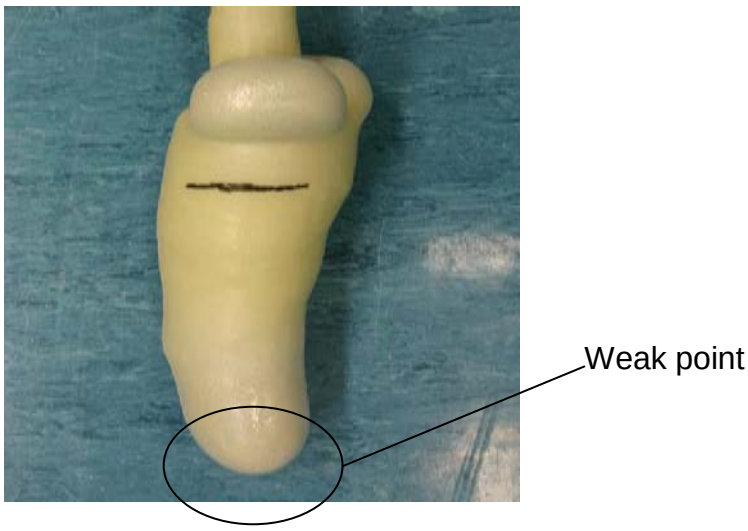


Figure 4.3 Overstretching of sand cast model. Latex coating of sand cast model is overstretching in the distal region (become transparent) even for medium-length residual limb.

After the field test, the investigation focuses on preserving the latex thickness at the end of the model and hence avoid burst. Finally, a simple tool called ‘casting rod’ was designed to solve the problem. The structure of casting rod was documented in Appendix A9. For the principle, there was a gap between circular ridge on the head of casting rod and a hollow cylinder to grasp the tip

of balloon and prevent it from stretching. The gap can be released manually by losing the nut on the handle of casting rod. When a latex balloons was put on the casting rod and pushed down without grasping, the stretching region of the balloon concentrated on the tip where become thin and transparent (Figure 4.4a). However, if the tip of balloon was gripped by the gap, the tip of balloon remains shrunk during by pushing down (Figure 4.4b). In the positive model forming process, the casting rod manually pushed down to the bottom of impression and the thickness of the tip of latex balloon was preserved by the rod. The nut on the handle was manually loose so that the tip of balloon was released from the gap when the latex balloon almost completely expands and lies on the impression wall. The latex coating on the tip region of model remained shrinking and the thickness was preserved. Figure 4.4c shows an extraordinary long dummy model which made with the modified SCM and casting rod, the coating on the top was thicker since it shows yellow in color, whereas the coating in lower end was over-stretched and become transparent. It demonstrates even in cases of extremely long residual limbs, the casting rod preserved the thickness of latex coating on the end of models. Thus, the casting rods get rid of the stretch-concentrating problem and the latex coating for long models become reliable. No long model bursted in the second field test in Beijing.

a b c

Figure 4.4 Effect of casting rod (a) a balloon was pushed downward along the casting rob without gripping and the stretching region focused on the tip and the latex coating became thinned and transparent. (b) The tip of balloon remained shrunk since it was gripped by the casting rod. (c) A long dummy model made according to SCM with casting rod, the top of model was yellow in color because the latex coating on the top was thick.

4.4.1.2 Performance of original prosthesis and monolimb

The AMP and PEQ scores of subjects with original and monolimb prosthesis were collected and shown in Table 4.3.

Table 4.3 AMP and PEQ scores with original and monolimb prosthesis

	AMP score		PEQ score	
Subject	Original	Monolimb	Original	Monolimb
1	29	40	50	75
2	33	42	60	85
3	30	41	45	70
4	32	43	55	80
5	31	39	40	70
6	30	43	50	80

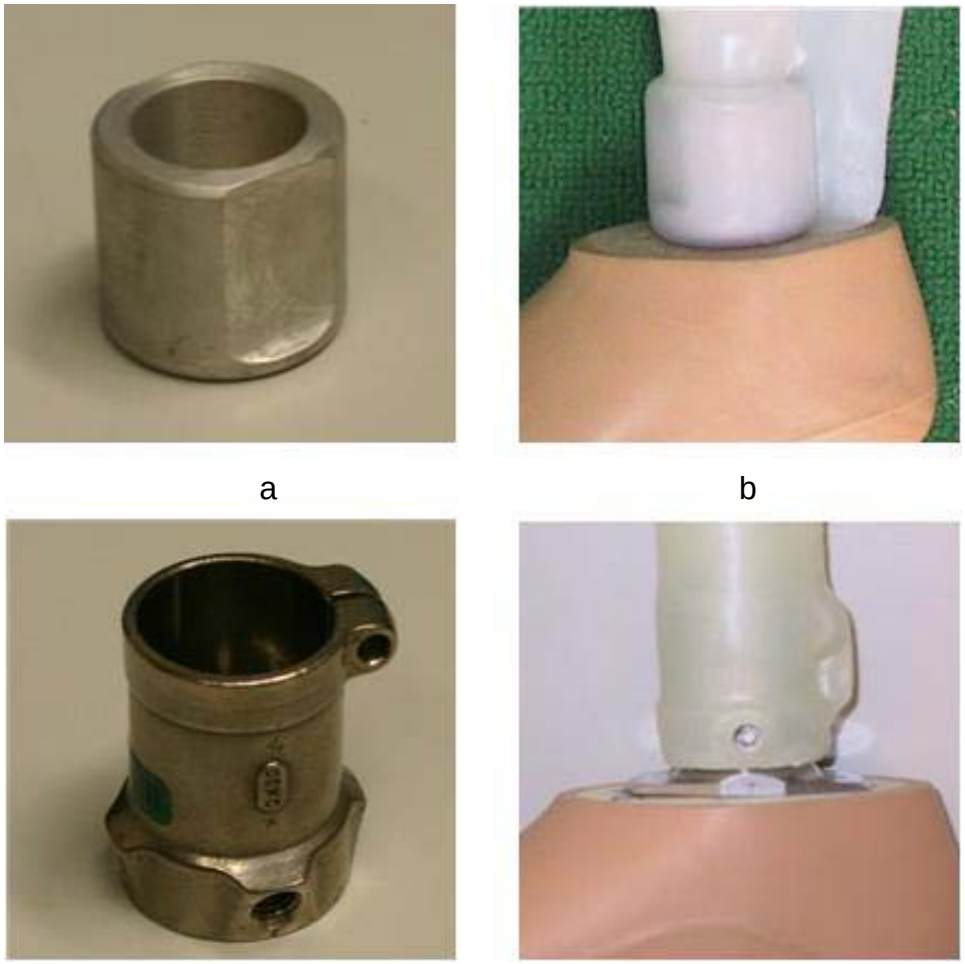
*The maximum score of AMP and PEQ is 47 and 100 respectively, high mark indicates positive result

Paired T-test was used to compared the results and found that the both the AMP and PEQ scores of monolimb were significantly higher than those of original prostheses ($p<0.0001$ in both case). The results suggested the modified SCM and monolimb prosthesis may improve the mobility performance and satisfaction of TT amputees in rural area.

4.4.2 Field Test in Beijing

In 2009, the improved method was presented in Beijing National Research Center for Rehabilitation Technical Aids for professional opinions. Nine amputees participated for demonstration. The technique was commented as fast and affordable, but the monolimb adaptor (Figure 4.5a) was unperfected since it allows only rotation of prosthetic foot (Figure 4.5b). Traditional

prosthetic foot adaptor (Figure 4.5c) was highly recommended to use instead of the original monolimb adaptor so that the alignment change was possible for the proceeding monolimb. Furthermore, employing a conventional prosthetic component instead of a custom-made monolimb adaptor should reduce the preparation work. Finally, the equipment and vacuum forming procedure were modified in Beijing so as to incorporate with conventional prosthetic adaptor as shown in Appendix A14. The cost of conventional adaptor was less than $150 HK dollars and the overall cost of monolimb was still affordable. Prosthetic foot of monolimb was able to perform dorsiflexion, plantar flexion, inversion and eversion in the same way of conventional TT prosthesis (Figure 4.5d).



a b

c d

Figure 4.5 Adaptation of conventional prosthetic connector in monolimb fabrication (a) Monolimb adaptor, (b) original monolimb, (c) traditional adaptor and (d) modified monolimb with traditional adaptor

CHAPTER 5 DISCUSSION

The dilatancy casting principle and monolimb were proposed for more than half century to simplify the procedures and reduce the cost of prosthetic production. Despite related studies have been progressing for decades, alternative affordable casting method and thermoplastic prostheses are still experimental (Thanh et al., 2009) and not widely applied clinically. This section indicates difficulties of the previous studies and discusses practical solutions provided in previous chapters.

5.1 Impervious Coatings for SCM

Impervious coating is one of the essential components for dilatancy casting principle since the shape and hardness of impression and model by air pressure gradient. However, the inventor, Warren et al. (1949) had not recommended suitable material as the constituent of coating. Perhaps limited materials were available for impervious coating 60 years ago.

5.1.1 Using Plastic Bag as Impervious Membrane

Until 1994, Wu suggested to use common and affordable plastic bags as the impervious coatings. However, our pilot experiments revealed the plastic bag coatings of both impressions and models were often pierced under vacuum pressure. Minor air leakage would be compensated by continuous air removal with vacuum pump. It explained why Jensen et al. (2005) suggested that “it depends on the vacuum machine and other electrically powered machinery working without power cuts throughout the entire working period”. Nevertheless, serious air leakage may not be compensated and eventually the impressions or models may rapidly collapse.

Furthermore, sand cast model with plastic bag coating may not be appropriate to thermoplastic vacuum forming for monolimb fabrication since plastic bag is liable to spoil under high temperature. Using thicker and stiffer plaster bag should enhance the safety, but it will also decrease the flexibility and hence the coating cannot completely lie on the residual limb and capture the shape. Wu et al. (2007) recommended using silicon-made casting bag to replace the original casting cylinder and plastic bag coating to increase convenience and security of the impression. However, the subsequent positive model was still proposed to be made of plastic bag coating (Figure 2.11). Wu et al. (2009) proposed to eliminate the use of plastic bag in the proceeding system for both impression and model. Nevertheless, the model in the casting bag is suggested to be made regressively of conventional plaster (Figure 2.12). Apart from the plastic bag coated model is unstable during thermoplastic vacuum forming procedures, there is other disadvantage of model concerning to alignment transfer which will be discussed in section 5.3.3.

5.1.2 Using Latex Balloon as Impervious Membrane

Wu et al. (2004) suggested using latex balloons as alternative impervious coatings for both impression and model instead of plastic bag (Patent 2004 U.S. 6,7096,17B2). However, neither the procedures of putting latex balloon on residual limb nor the purpose was specified. In fact, latex membrane provides excellent air sealing feature and incredible elasticity of coating that common plastic bag can never commit. Besides, pilot experiment showed the latex coating effectively resists melting in the thermoplastic vacuum forming procedure. The challenge is how to put a common latex balloon on

residual limb evenly. By observing latex balloon is uniformly stretched during inflation (Figure 3.1), it gives a hint to stretch latex membrane uniformly by air pressure difference. If a sheet of latex membrane can be moulded on the month of casting cylinder, the membrane will be elongated along the cylinder evenly by suction and ready to uniformly envelope residual limb. However, the recoil force of the latex is strong under stretching and it was difficult to mechanically clamp a thin latex sheet on an opening of a hollow tube with air sealing feature for suction. Possibly, it was the reason why the latex coating for SCM was proposed but never used in previous studies. The current study found common double side adhesive tape provides an affordable and simple way to secure the latex balloon firmly on the mouth of cylinder with air sealing feature. Latex cap moulded on the opening of a hollow cylinder tends to recoil and return to this un-stretched shape. However, the tape around the opening provides high adhesive force to resist the stretching latex membrane slide along the surface. As a result, stretched latex cap can be fixed and sealed the opening of cylinder (Figure 3.7a). Contradictorily, the latex membrane can be easily removed from the tape surface by peeling perpendicularly with hand. In summary, we found it is a simple method to envelop residual with latex balloon as impervious membrane for SCM instead as illustrated in Section 4.5.7 and Appendix A6.

5.2 Rectification of Sand Cast Model

The result of dimension comparison experiment (Table 4.1 and 4.2) indicated the models made according to original SCM proposed by Wu (2001) were larger than residual limb in girths. It explained why Jensen (2005) found the

sockets made according to the method were loose. Moreover, Wu et al. (2004) suggested that indentations of sand cast model were achieved by hammering on model (Figure 2.10). Perhaps fragile plastic bag and hence the entire sand cast model were usually destructed by this aggressive rectification method, Wu (2009) proposed to skip the rectification procedure and alternatively fabricate prosthetic socket with total contact approach. However, it may be inapplicable to most of residual limbs with pressure intolerant regions (Section 2.3.3). This section clarifies the size and shape problems of SCM models and explains the solution provided in section 4.5.

5.2.1 'Shrinkage Effect' of SCM

Small granules were filled into the casting cylinder in the impression moulding procedure. It is believed the granules were packed loosely and there is a considerable amount of space among the granules. During the first vacuum process (Figure 3.4), granules were pushed by the atmospheric pressure and move to surrounding gaps for rearrangement. Consequently, the granules packed denser and the total volume occupied by the granules reduced, it was so-called 'shrinkage effect'. As the total volume of glass beads in the cylinder shrank, the volume of impression cavity and hence that of model increased. Thanh et al. (2009) suggested analogous explanation for the loose socket problem.

We suggest the problem may be partially reduced by gently shaking the casting cylinder while the granules are filling into the acrylic cylinder. The method reduces the space among granules and diminishes the shrinkage effect. Nevertheless, the shrinkage problem was chiefly solved by the

bandage wrapping technique (Section 4.5.8) and it is discussed in the following section.

5.2.2 Girth Reduction by Bandage Wrapping

Wu (2004) suggested wrapping bandage around residual limb (Patent 2004 U.S. 6,7096,17B2), but the result was not evaluated. As discussed previously, our pilot study proved that common plastic bags were too slippery to hold the bandages in position. It explained why wrapping bandage technique was proposed but not practically applied in previous studies.

However, we found that the surface of latex balloon provided sufficient friction so that the bandage could be firmly wrapped on the cylindrical residual limb without slipping. Although the strong recoil force of latex cap always compresses the residual limb to be substantially shorter and thicker, the squeezing force of bandage not only counterbalance the recoil force of latex cap, but also squeeze proximal soft tissue to the distal end. The shrinkage effect was compensated by thinning of residual limb with bandage wrapping technique. The method reduced the girths of models as proven in the dimension comparison experiment and firmer sockets were obtained in the succeeding trials.

5.2.3 Indentation of Sand Casted Model

In conventional plaster casting procedure, indentations made on impression over patella tendon and popliteal region by compressing with thumbs and fingers (Section 2.2.1.2). Hence, the depths of indentations depend on the depth and stiffness of the soft tissue and excessive indentation can be

avoided basically. However, original SCM proposed indentation to be made by hammering on sand cast model. Apart from the high chance of damaging fragile plastic bag coating and causing severe air leakage, it is difficult to control the depth and shape of indentation. Excessive and insufficient indentations may be easily resulted since the sand casted model provides no information about the depth and stiffness of soft tissue. Furthermore, the hammering or pressing method does not reduce the volume of model, but the granules were pushed and move to the surrounding area. It causes unnecessary built-up around the indentation region.

The wrapping bandage technique presented in the current study not only reduced the girths of model, but also provided a convenient method to make indentations. In the casting procedure shown in section 4.5.8, pads for indentation were stacked over the patella tendon and popliteal region on the latex cap. The residual limb was then tightly wrapped by bandage and the pads are pressed against the soft tissue and made indentation shape. Similar to the conventional hand casting procedures with plaster bandage, the depths of indentations depend on the depth and stiffness of soft tissue and excessive indentation can be avoided. In short, bandage wrapping method reduces the girth and makes indentations on model to prevent loose socket. And it requires low technique and experience compared with making indentations on conventional plaster model.

5.3 Monolimb Alignment

The main disadvantage of monolimb is that the prosthetic alignment should be decided in the fabrication procedure and no modification is allowed after manufacture (Section 2.3.1.3). Several approaches such as ABA and VAA

were proposed to determine promising bench alignment. Vecchiotti et al. (2004) suggested the outcomes were not satisfactory enough for clinical use. Wu's proceeding casting bag in 2007 (Figure 2.11) simplifies the casting procedure, but it provide no alignment information. Although Wu's casting and alignment system patented in 2009 (Figure 2.12) provides a temporary prosthesis to determine static and dynamic alignment in the impression casting procedures, the opaque and bulky casting bag properly hides the position of residual limb with respect to the pylon. Moreover, conventional plaster model, rather than fast and low cost SCM, is proposed in Wu's system for proceeding alignment transfer.

In the current suggested solution, the wall of temporary prosthesis is made of transparent acrylic cylinders and the orientation of residual limb in the cylinder can be clearly observed in sagittal and coronal planes before filling granules (Section 4.5.9). The position and alignment of the residual limb can be adjusted easily by shifting and titling of residual limb. It provides an effective method to assign the static alignment. The temporary socket is ready for dynamic alignment after first vacuum (Section 4.5.12). Furthermore, for conventional monolimbs, pylon should be perpendicularly attached to the prosthetic foot (Figure 2.2) and only the proximal pylon adaptor of the temporary prosthesis can be adjusted for dynamic alignment. In the presenting monolimb, however, conventional prosthetic adaptor instead of monolimb adaptor (Figure 4.5) is used in both temporary prostheses and the succeeding definitive monolimb. Prosthetic foot alignment of monolimb is adjustable in the same way of conventional prosthesis. Although the proposed solution increases the monolimb manufacture cost by using

conventional prosthetic components (prosthetic pyramid and pylon connector), the preparation work of the custom made monolimb adaptor can be eliminated. Moreover, the alternative components may cost as low as $150 Hong Kong dollars. The overall cost of new type of monolimb is still affordable.

5.4 Distinctions of Casting Methods for Dimension Comparison and Monolimb Fabrication

It should reminded the procedures of SCM for dimension measurements in section 3.2.2 and monolimb fabrications method in section 4.5 are different because proceeding monolimb fabrication cannot be achieved by original method. This section reviews the differences and technical problems of monolimb fabrication with original SCM and explained how they are solved by modifications.

5.4.1 Latex Cap Holding on Residual Limb

In the dimension comparison experiment, latex cap was directly stacked on the casting cylinder for suction to evenly envelope the residual limb (Figure 3.7). The latex cap was then detached from the cylinder and stacked on double side tape around the mid patella level. It was found that the adhesive tape on the residual limb shift distally with the underneath soft tissue by the recoil force of latex cap and finally the latex cap retracted for about 1cm. Since the boundary of latex cap was still higher than patella level after retraction and the reference lines R were marked on the bandage (Figure 3.2), the shrinkage did not affect the accuracy. However, in the procedures of making sand cast model for monolimb manufacture, the latex cap contracted and caused dislocation of pads for both pressure-relieves and

indentations. In addition, the boundary of latex cap rarely reached the supracondylar level of knee after retraction especially for cases of long residual limb, and hence obstructed forming the supracondylar indentation feature for self-suspension.

Eventually, the problem of latex cap retraction was solved by stacking latex cap on a fixed acrylic ring (Section 4.5.7 and Appendix A6). The latex cap shrinkage was prevented by attaching the latex cap boundary on a ring fixed proximally to provide a pushing force and hence prevented the cap from shrinkage.

5.4.2 Granules for the Experiment and Monolimb Casting

In the model dimension comparison experiment, spherical glass beads with 0.8mm in diameter were used as granules for both impression and model formation (Figure 3.3). However, as illustrated in section 4.5.10, plastic beads were used instead of glass beads for impression formation. Initially, original glass beads were used as stuff for temporary socket formation in temporary prosthesis, but the ‘glass bead socket’ was too heavy for ambulation. The glass beads should be replaced by lightweight, rigid, and reusable tiny alternatives to reduce the weight of temporary prosthesis.

Finally, spherical plastic beads with 2mm in diameter were used instead. The price of the beads was inexpensive since they were actually a simple toy to make necklaces or adornment by connecting series of beads by strings. Apart from the lighter mass of the plastic, there was a hollow canal with 1mm diameter in each of plastic bead, and its weight was about only one-fourth of glass bead. In addition, although large granules reduced the smoothness of impression, the elastic bandage surrounding the latex

membrane provided a buffer or filter to reduce the coarseness. As a result, the impressions made of plastic beads are undistinguishable from that made of glass beads in terms of flatness on the wall of impression.

5.4.3 Casting Rod

In the dimension comparison experiment, all the subjects were amputated in TT level and had middle length residual limb. Probably it was because TT amputations in Hong Kong were operated in common posterior flap surgical procedure (Section 2.1.2). No cases with long residual limb and hence no over-stretching of residual limb model presented in the dimension comparison experiment. However, some of the TT amputation level in mainland China is much lower than that in Hong Kong. There is a perception in Chinese that it is good to retain the residual limb as much as possible. Consequently, the residual limbs in the field tests were usually too long and the latex balloons of models were over-stretched in the apex region and finally burst (Figure 4.3). The casting rod (Appendix A9) was developed and used in residual limb model forming procedure (Figure 4.4) to solve the over-stretching problem.

5.4.4 Funnel on Casting Mandrel

In the thermoplastic vacuum forming procedures, the sand casted model, pylon and monolimb adaptor (foot blot) were fixed on the alignment jig firmly so that the height and alignment of the temporary prosthesis could be transferred to the monolimb accurately. However, all the monolimbs made according to Wu's SCM (2004) were shorter by about 1cm. Finally, it was found that during the thermoplastic sheet encapsulated the SCM in vacuum forming procedure, the thermoplastic cooled down, retracted and pushed the

sand casted model towards the pylon direction. And eventually the consequent monolimb is shorter than expected.

The problem was finally solved by adding a funnel-shaped stopper on the suction mandrel to act as an obstruction, which prevented the sand casted model to slide along the mandrel (Section 5.5.15 and Appendix A8). The simple device effectively maintained the height of monolimb during the thermoplastic vacuum forming procedure.

5.5 Comparisons of Wu's Casting and Alignment System and the Suggested Method in Current Study

Both Wu's sand casting and alignment system (2009) and the presenting monolimb fabrication procedures provides temporary prostheses to capture impression of residual limb and assign static and dynamic alignments for monolimb fabrication. This section compares the two systems in different aspects.

5.5.1 Impression Moulding of Residual Limb

The casting bag captures the impression of residual limb and provides a temporary socket for alignment assignment as illustrated in Figure 2.12. The bag simplify the casting procedure by simply rolling the casting bag on residual limb and eliminates equipment such as casting cylinder and granules for stuffs of impression filling. However, the invention offers no solution to the shrinkage problem (Section 5.2.1). The volume of casting bag reduces after vacuum and hence the volume of impression cavity increases. Ultimately, the proceeding socket is expected to be loose. Bandage wrapping technique is not compatible to the casting bag since the whole residual limb

is first embraced by the bag filled with granules. Besides, indentations over the pressure tolerant regions on the model cannot be achieved by the bandage method illustrated in section 4.5.8, since no squeezing force pushes the pads on the residual limb. In addition, second vacuum described in section 4.5.14 is not feasible for casting bag. When the pressure of impression cavity was reduced to suck down the casting balloon, the pressure on the outer wall of casting bag would be greater than that of the inner wall (cavity) and impression would be collapsed by the unbalance pressure.

Respecting to the presenting cast method, the shrinkage effect is counterbalanced by bandage wrapping technique, which also provides a squeezing force to push pads on the residual limb to form indentations. The wall of temporary prosthesis is made of two rigid acrylic tubes rather than soft silicon membrane, so the shape of temporary socket is not changed by the second vacuum.

5.5.2 Modification of Residual Limb Models

Residual limb modeling according to SCM is still proposed for standalone casting bag in 2007 (Figure 2.11). However, the residual limb model (Figure 2.12) is proposed to be made of conventional plaster in Wu's sand casting and alignment system (2009). It is contradictory to the original SCM, which suggests casting and modeling without plaster to reduce fabrication time and material cost. Moreover, since indentations of plaster model should be achieved by experienced and time-consuming plaster rectification rather than simply hammering and pressing in original SCM (Figure 2.10), total contact socket (Section 2.2.1.1) is suggested instead to eliminate the plaster

rectification procedure. However, the total contact design is only suitable for residual limb with round and thick tissue surrounding, and modal modification is essential for most of the residual limbs in general (Section 2.2). The reasons of retrogression are partially discussed before, as plastic bag is not tough and unreliable against high temperature in the vacuum forming process. In addition, the resultant monolimb might be shorter since there was not feature equivalent to the funnel described in section 5.4.4 to prevent the sand cast model from sliding along the mandrel. Nevertheless, the main cause of refusing long-proposed SCM regards to the pylon of proceeding monolimb as discuss in the section 5.5.3.

For the presenting casting method, sand casting residual limb model is chosen to provide economical casting method for rural areas.

5.5.3 Pylon

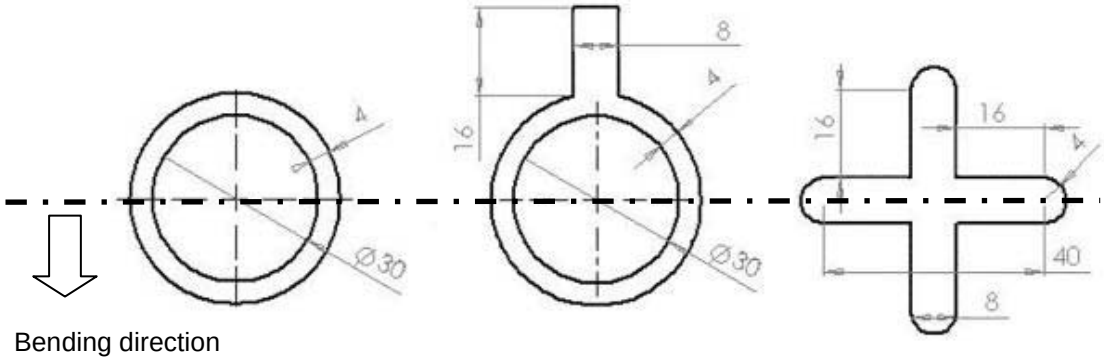
The X-shape pylon has the most distinctive feature of monolimb fabrication according to Wu's casting and alignment method (Figure 2.12). In our pilot studies, conventional aluminum prosthetic pylon was used as dummy of monolimb pylon in thermoplastic vacuum forming. However, the dummy often jammed in the thermoplastic pylon of monolimb since the negative pressure in vacuum forming process and the contraction of the thermoplastic squeeze the cylinder too tight to be pushed out. As a result, the dummies stayed in most of the monolimb and the cost and weight were increased. Perhaps Wu avoided this problem by not using rigid cylinder as dummy but two common strings instead. The strings formed two closed loops and tightly connected the model to the foot bolt so that the loops become a rigid bridge to support the thermoplastic sheet against contraction force during the

thermoplastic vacuum forming process (Figure 2.12). Since the strings were low-cost and light in weight, it was not necessary to remove the strings from the monolimb. However, there should be holes on the model so that the strings can pass though and form a close loop tightly. It was inappropriate to drill through the sand cast model since the shape of model was maintained by air pressure difference. Eventually, SCM for residual limb modeling was abandoned and the model was made of conventional plaster instead.

In the present study, the aluminum dummy was covered by double layers of tubular cloth saturated with lime powder (section 4.5.17). The configuration not only provided a lubricant layer for the removal of the dummy, but also served as air passage of sir during thermoplastic vacuum forming process. And more importantly, the vacuum forming mandrel was specified and the dummy pylon should be able to be pushed out from the monolimb by hitting on it (section 4.5.20 and Appendix 14). The light weight and low cost of monolimb was retained without employing the X-shaped pylon approach.

Previous findings addressed that the flexible pylon of monolimb provided an energy storing mechanism and promoted ambulation (Section 2.3.1.2). However, the feature was not considered for the monolimb presented in the current study due to alternated structures. Previous studies considered the shape of pylon was cylindrical, but there was a ridge in the welding region of the present monolimb (Figure 4.2a and section 4.5.20.) The function of the ridge is to increase the bonding area of thermoplastic and prevent it from splitting. In addition, the ridge provides an extra stiffness for the pylon against bending in coronal plan. If the thickness of the thermoplastic is uniformly 4 mm after vacuum forming and the height of ridge is 16 mm, the cross

sections and moment of inertia of cylindrical, ridged and x-shape pylons are shown in Figure 5.1.



a b c

Figure 5.1 Cross sections and the second moment of inertia (I) of different pylons (a) hollow tube pylon with I=62594mm^4 (b) ridged pylon with I=134514mm^4 and (c) x-shape pylon with I= 67954mm^4

The second moment of inertia of circular and x-shaped pylon are similar (67954/62593=1.08), and that of ridge shaped pylon is about 2 times than the other (134514/62593=2.15). The pylon with ridge in current study is considered to be much rigid than the pure cylindrical pylon and the flexibility is ignored. In fact, previous studies only consider how the shape of pylon affects flexibility (Lee et al., 2004), but the effects on the length of pylon and body weight were not considered. For the cases of long pylon and high body weight, the pylon may be too soft and cause excessive flexion. Finally, the performance of ambulation and the life-span of monolimb may be deteriorated. The present study suggested rigid pylon is preferable since the flexibility of pylon is difficult to control by shape.

5.5.4 Suspension

According to Wu's casting and alignment system (2009), temporary prosthesis was self-suspended by rolling the casting bag over supracondylar region and gets the contour of femoral grooves after hardening (Figure 2.12). However, the soft bag cannot apply sufficient force over the supracondylar region and form the indentation shape. Sleeve suspension is recommended for the succeeding monolimb. Sleeve provides a simple and quick solution for prosthetic suspension, but the drawbacks include perspiration, restriction of knee movement and contradictory to poor circulatory function. Besides, once the sleeve loses the elasticity, it cannot securely hold the monolimb and should be renewed periodically (Section 2.2.5.1).

In the presenting casting method, the temporary prosthesis consisted of a pair of supracondylar pads (Figure 4.1 and Appendix A13) which not only connected and fixed the position of the residual limb relative to socket, but also provided sufficient pressure over the supracondylar region of the knee to form indentation shape. Temporarily prosthesis and the succeeding monolimb can self-suspense on the residual limb. The width between the supracondylar cushions can be adjusted by horizontal screws. The technique in the current study provided a self-suspended monolimb and the cost for sleeve was also eliminated.

5.6 Limitation and Improvement of Presenting Casting Method

A few improvements are suggested to increase the efficiency of the presenting casting method. However, it will increase the set-up cost and technique since some of the suggested equipment is custom-made and may be relatively expensive.

5.6.1 Shrinkage Effect of Plastic Beads

It was found that impressions made with plastic beads with 2mm diameter suffered more serious shrinkage effect than those made with glass beads in 0.8mm in diameter. It is simple because the plastic beads used in this study were larger in size and hence increased the space among the plastic beads. The impression made of plastic beads was then more compressible and the cavity of impression became larger after vacuum. Hence, the temporary prosthesis may be loose. Although it was found that the shrinkage effect can be diminished by shaking the socket while filling with granules, it should be gentle and patient to avoid dislocation or misalignment since the amputee is standing on the prosthesis and maintaining the static alignment (Section 4.5.10). Besides, the weight of temporary prosthesis filled with plastic beads was still even heavier than conventional prosthesis. It is recommended to use smaller and lighter plastic beads to reduce the space among the beads and the weight of temporary prosthesis.

5.6.2 Size Limitation of Residual Limb

Preliminary trials found the proposed method produced loosen socket for thick or edema residual limbs. The broadened distal end of residual limb obstructed the filling of plastic beads and consequently decreased the density

of plastic beads in the temporary prosthesis. Hence, the shrinkage effect progressed and the impression and model would be larger in size and eventually the socket would be loose. The problem may be solved by using smaller granules for denser granule packing. The present cast model is unsuitable to bulbous shaped residual limbs.

5.6.3 Maximum Loading of Monolimb

When thermoplastic sheet is wrapping on monolimb model in the vacuum forming procedure, the soften sheet will inevitably be thinned by its own weight and stretching (section 5.5.18). Generally, the original 5mm-thick thermoplastic will be thinned to form monolimb with wall thickness of about 4mm. Lee et al. (2006), our pilot studies and field tests indicated the monolimb with 4mm wall thickness can support amputee with at about 70kg body weight. However, insufficient wall thickness may be resulted if the thermoplastic was overstretched or overheated (too soft) in the vacuum forming procedure. In these cases, subject will find that the monolimb is shorter because the medio-lateral brim of the supracondylar socket is not rigid enough to support the body weight during weight bearing. The socket eventually deforms and the residual limb sinks during weight bearing. It can be easily clarified if the width between medial and lateral supracondylar regions of monolimb is widened during weight bearing condition. Similar finding was reported by Convery et al. (1988), which claimed that some branches of thermoplastic sheets (all made of polypropylene) were not rigid enough to support moderate body weight bearing, as the mechanical properties may be different from manufactures. The thermoplastic (Polystone^{TM}) used in current study provided sufficient strength to deal with

moderate body weight up to 70 kg. The recommended method of increasing the rigidity of monolimb is to simply make 2 to 3 vertical ridges or ripples on each medial and lateral side of the socket during vacuum forming. The ridges increase the second moment of inertia and hence rigidity of socket to resist deformation. Although the appearance of monolimb may be deteriorated by the non-streamline shape, it is the simplest approach to increase the strength of socket without additional material or equipment is involved.

5.6.4 Substitutes for Latex Band and Supracondylar Clamp

Latex band made by trimming the both ends of balloon serves as a simple, cheap and reliable air-sealing membrane for both ends of acrylic tube (section 4.5.2 and 4.5.5). However, masking tape and double side tape should be first stacked on the both ends of lower tube and the lower end of upper tube so that the latex bands can attach the tubes. It may increase the preparation time for casting procedure, and the latex bands may not be reusable if they are damaged in the demolding procedure (section 4.5.16). Reusable silicon rings (Figure 5.2) are recommended instead of latex band to save time and material cost. The other possible improvement regards to the height adjustment of the pair of supracondylar clamps. Although different length of screws can be used to adjust the length of supracondylar clamps (Appendix A13), it is messy to replace screws with different length during adjustment. It is proposed to use a rod with adjustable length instead of a conventional screw in the supracondylar clamps so that the position of supracondylar pad can be easily adjusted for individuals. However, both the equipment of silicon rings and adjustable rod are no available in the market and should be custom-made. It will increase the cost and complexity in the

set-up process. In brief, the casting and vacuum forming procedure can be simplified and become more effective if more investment is involved in the set-up process.

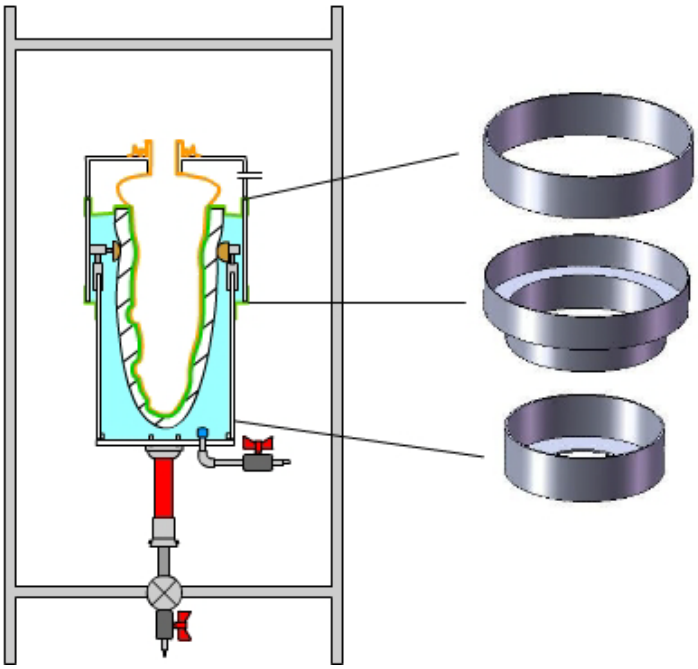


Figure 5.2 Reusable elastic and impervious rings are suggested to connect the acrylic tubes instead latex band to simplify the casting procedures.

5.7 Promotion Plan

In summary, the presenting technique provides an economical alternative to fabricate TT monolimb with ordinary items rather than specialized prosthetic equipment. The simplified casting and fabrication procedures reduce both difficulty and length of the training course, therefore more people can be equipped to contribute for the TT amputated disables. Nonetheless, in my opinion, the simplicity of presenting technique may cause benefit conflict. Prosthetic service is definitely a business in modern societies or people will not put large investment for cutting edge prosthetic design and production. Even in some developing countries, such as China, a conventional TT prosthesis may charge for more than 30 thousands Hong Kong dollars. The present technique promoting common items as substitutes of professional prosthetic components and tools is undoubtedly offending the profit for prosthetists, medical sales and component manufacturers. Furthermore, the simplified procedures of presenting technique may offer a greater chance for dilettantes to voluntarily provide prosthetic service and hence reduce the professionalism of prosthetists.

CHAPTER 6 CONCLUSION AND FUTURE WORK

6.1 Conclusion

The modified SCM and thermoplastic vacuum forming prosthesis presented in the current study is a suitable alternative approach to deliver supracondylar TT prosthetic service in rural area. Latex balloons are preferred to use as impervious coating instead of plastic bag in SCM to effectively reduce the chance of air leakage. The dimensional comparison experiment indicated models made according to original SCM were significantly larger than residual limb, and it can be solved by using latex coating wrapped with bandage instead of plastic bag. Pilot study and field tests indicated the method solved the loose socket problem. For the suspension system, self-suspension method was introduced to SCM, which originally relied on auxiliary suspension system such as sleeve. With respect to components of monolimb and material used in the procedures, the socket and pylon of monolimb were made of a piece of thermoplastic and a conventional prosthetic adaptor, which cost less than HK $200, and so the weight of monolimb was much lighter than conventional resin-laminated prosthesis. Custom made pelite liner was replaced by washable sports socks available in market for soft cushion between residual limb and prosthetic socket. Although the vacuum pump and oven for thermoplastic vacuum forming are relatively expansive, these equipment are reusable with long life span. A few of the tools are not available in markets, such as vacuum cap and supracondylar cushions, can be custom-made in common workshops

with affordable cost and simple technique. The only consumable used in the casting procedures such as latex balloons and adhesive tapes are inexpensive. As a whole, a long list of consumable (including plaster, plaster bandage, pelite, PVA bags for resin lamination, resin, glass fibre, Perlon, metallic pylon and prosthetic adaptors for socket-pylon connection) is replaced by affordable latex balloons, adhesive tapes, thermoplastic and a pair of sports socks. Cost of administration is also saved by reducing components involved in the procedure. Regarding to manpower, the time of training can be shortened for weeks since no plaster modification is involved in the procedures. The field tests evidenced economical monolimb can be described for TT amputee in a single-day visit for long term use. It is expected a functional and affordable TT prosthesis can be delivered by a trainee with less experience and resource according to the suggested method.

6.2 Future Work

It is recommended to advance the current study and technology in the following research directions:

1. Monolimb with original adaptor (Figure 4.5a) passed mechanical tests performed in previous study. However, mechanical tests for monolimb with conventional adaptor proposed in current study are not yet performed. It is suggested to examine the new type of monolimb according to ISO 10328 whether the presented moulding method is strong enough to hold the conventional adaptor in the thermoplastic for repeated loading. Alternative materials, such as transparent Thermolyne used in traditional prosthetic check socket forming, may be used instead of polypropylene to provide the

monolimb stronger stiffness to avoid deformation under high loading. However, it may increase cost and weight of monolimb.

2. Socket-residual interface pressure of conventional prostheses and monolimb obtained should be compared. The pressure data can be collected by flexible pressure sensors, such as Tekscan, to determine the contact area, proper fit and pressure contribution of the monolimb socket for evaluation.

3. Kinematic data of monolimb can be collected using motion capture system, such as Vicon system for gait analysis to verify and improve monolimb alignment method.

4. The performance of monolimb with conventional prosthetic adaptor is not yet validated. It is proposed to conduct within-subject experiments to compare the monolimb and conventional prosthesis performances in terms of comfort and frequency of use. Both types of prostheses are advised to distribute to amputees reciprocally for two weeks or longer. The comfort and frequency of use of each kind of prostheses can be recorded by questionnaire and step counter for comparison.

5. Whether the presenting method may apply to trans-femoral residual limb should be investigated.

6. Pre-fabricated prosthetic foot may be replaced to further reduce the cost of monolimb.

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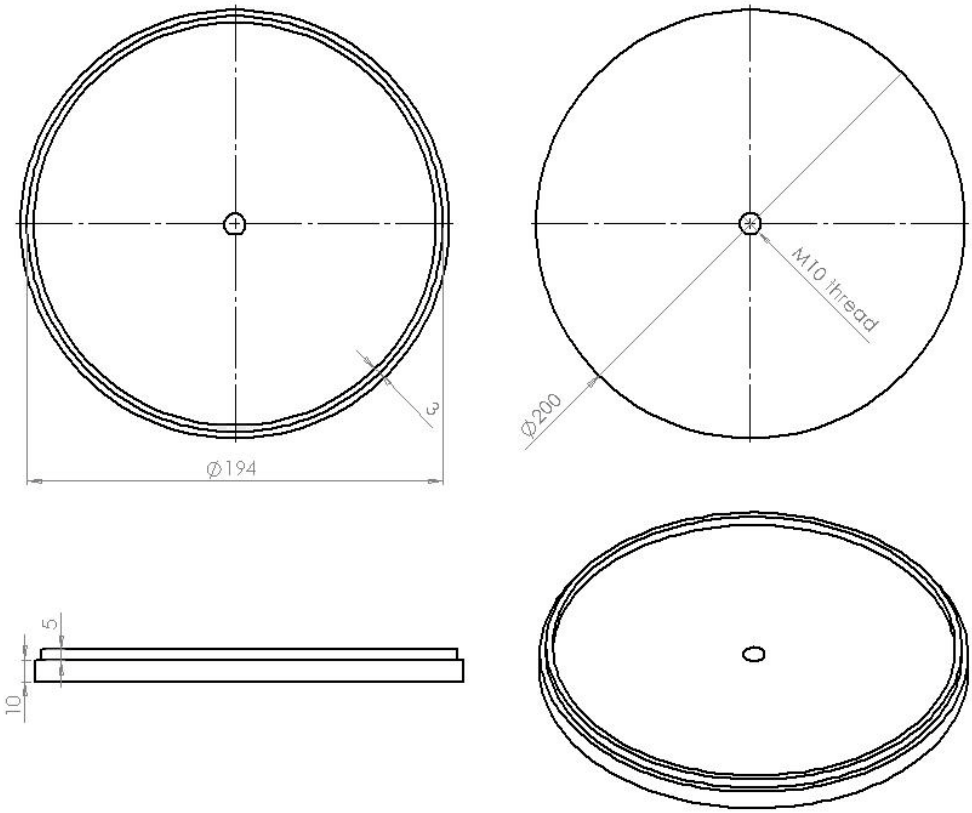
APPENDIX A Structures of custom made equipment

A1. Vacuum base (Large)



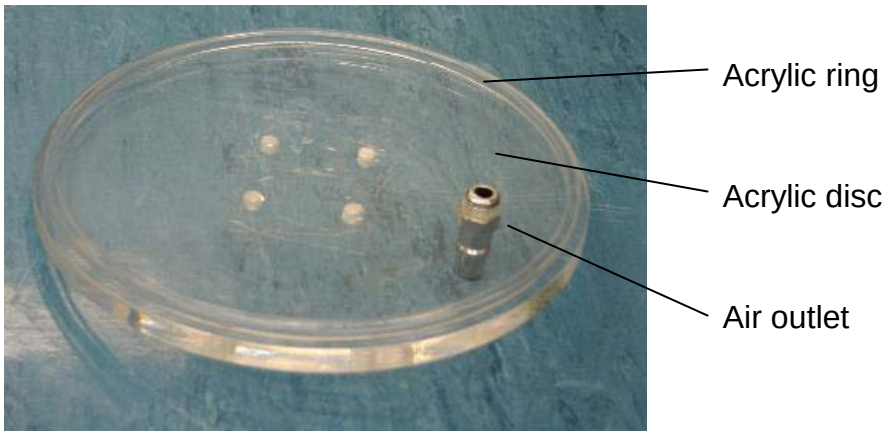
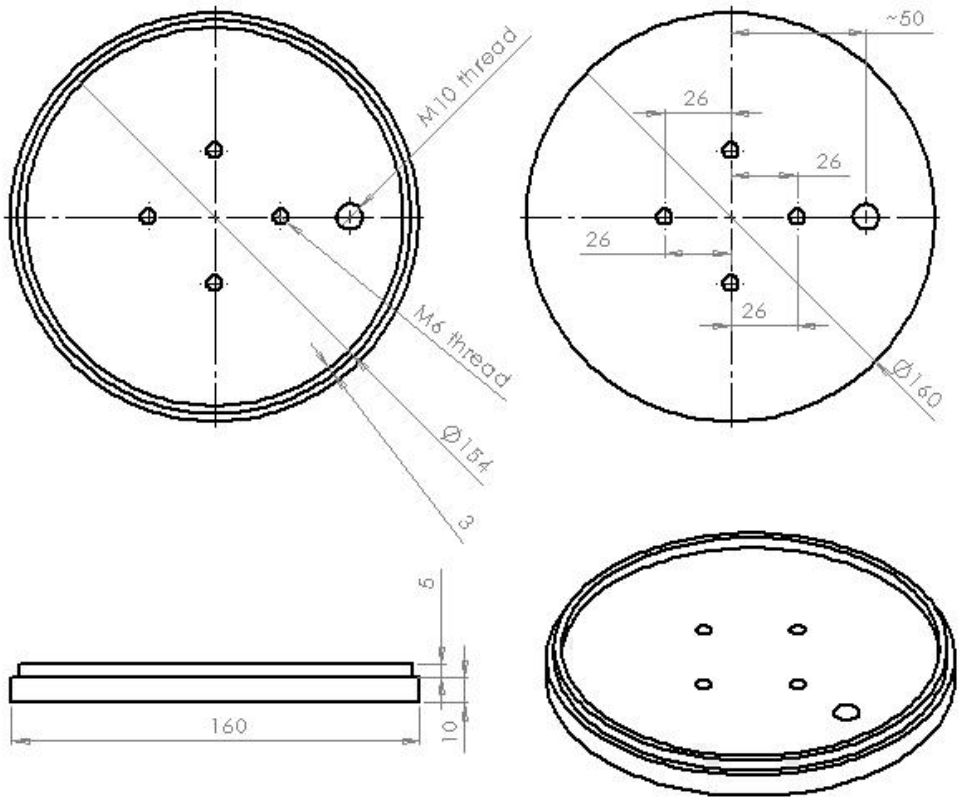


Figure A1. A circular plastic plate connects the end of acrylic tube for suction. The cylinder ridge on the top prevents the connecting plastic tube from dislocation and the air outlet connects to the vacuum source. See Appendix

A2. Vacuum base (Small)



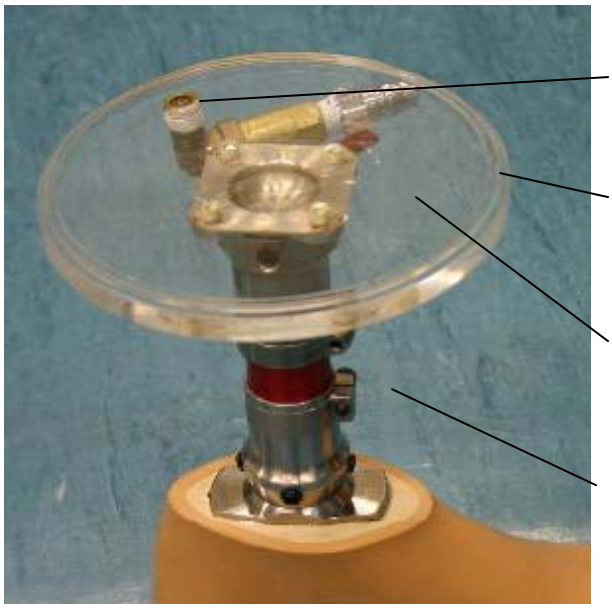


Figure A1. A small cylinder plastic plate is the base of temporary socket which connects conventional prosthetic components and air outlet.

A3. Acrylic ring, worm gear clamp for latex cap suspension

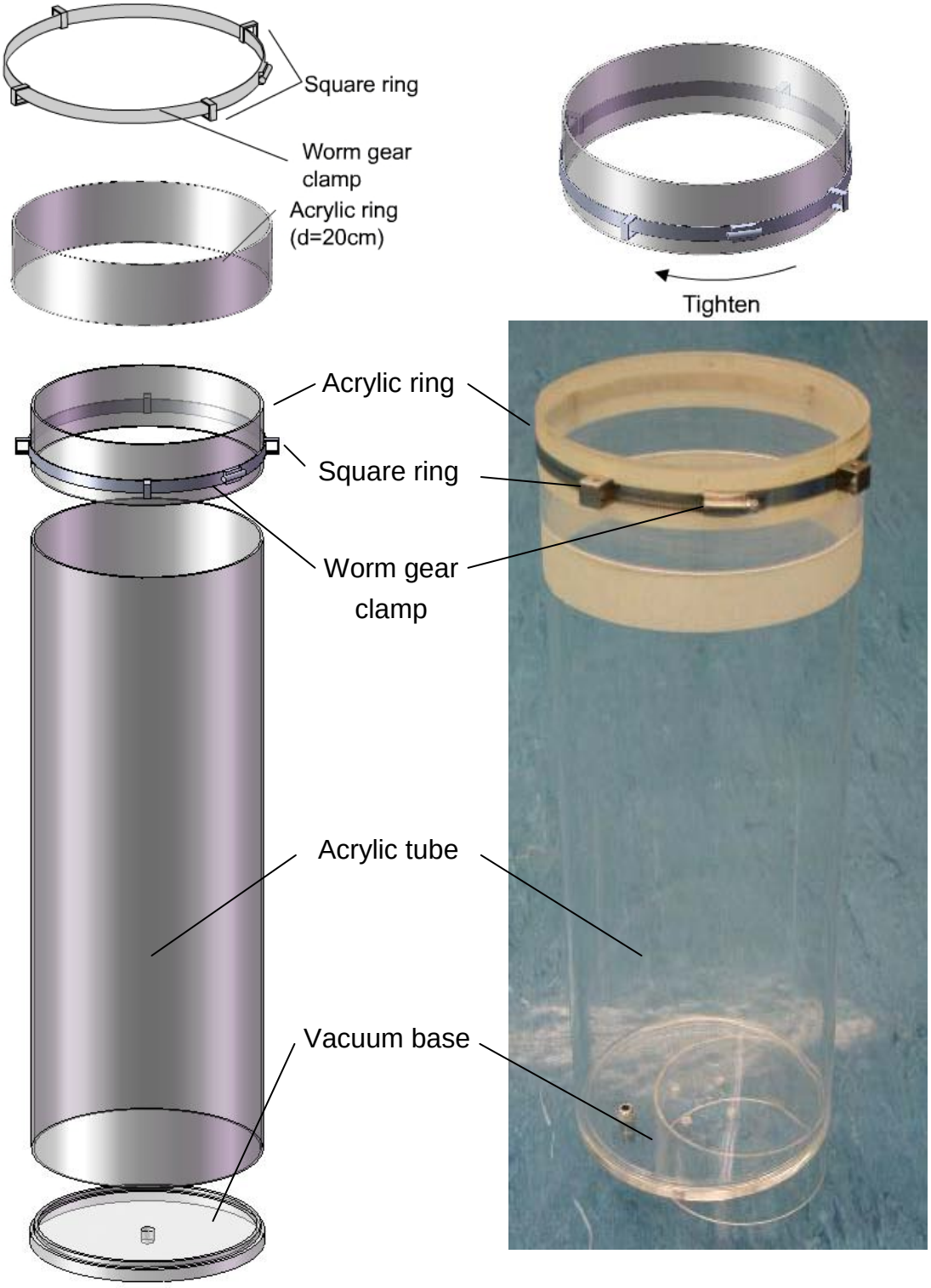


Figure A3. The acrylic ring and tube is connected and air sealed by common masking tape. The vacuum base attaches to the acrylic tube with latex band described in Appendix A4

A4. Latex band air sealing

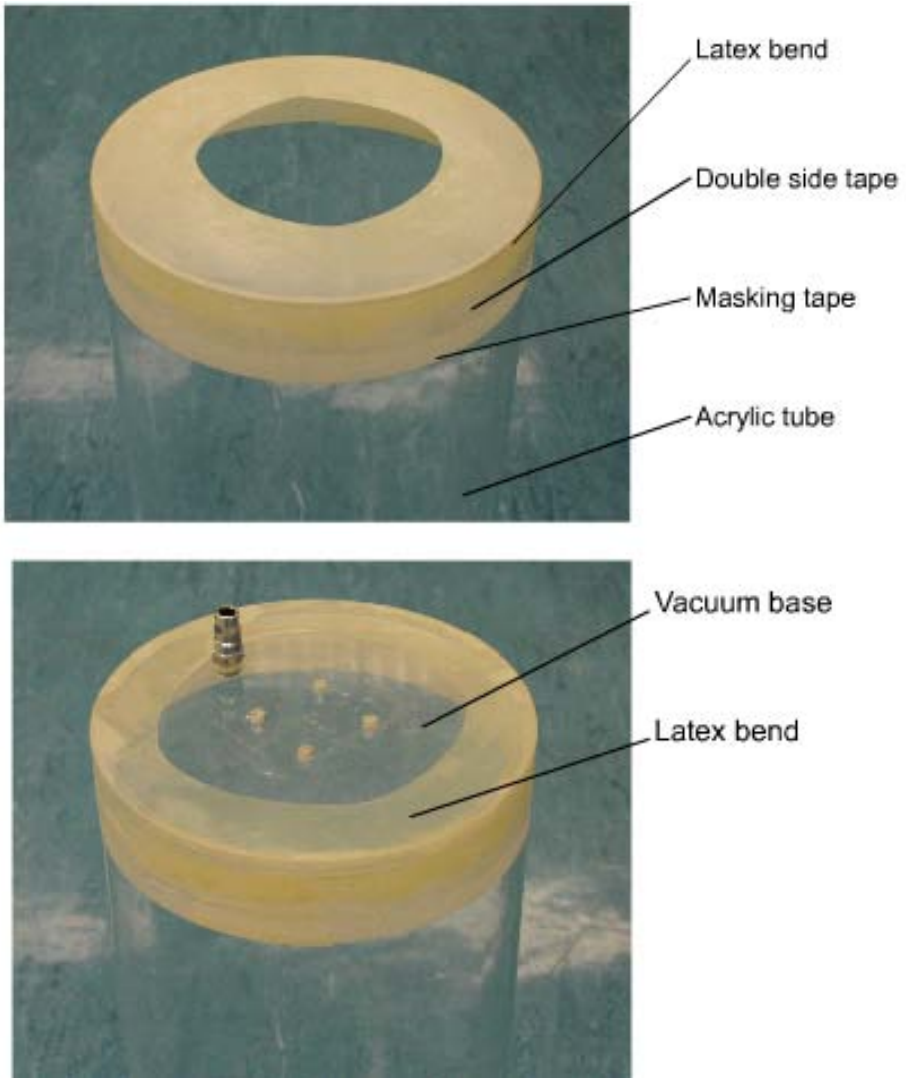


Figure A4. Latex band and latex cap can be fixed on acrylic tube by stacking with double side tape. Making tape is placed between so that the double side tape can be removed from the tube easily. Vacuum base on the tube is hold and air sealed by wrapping with the latex band. Air sealing feature can be enhanced by moistening the gap between the bend and vacuum base.

A5. Pads for pressure relieves and indentation

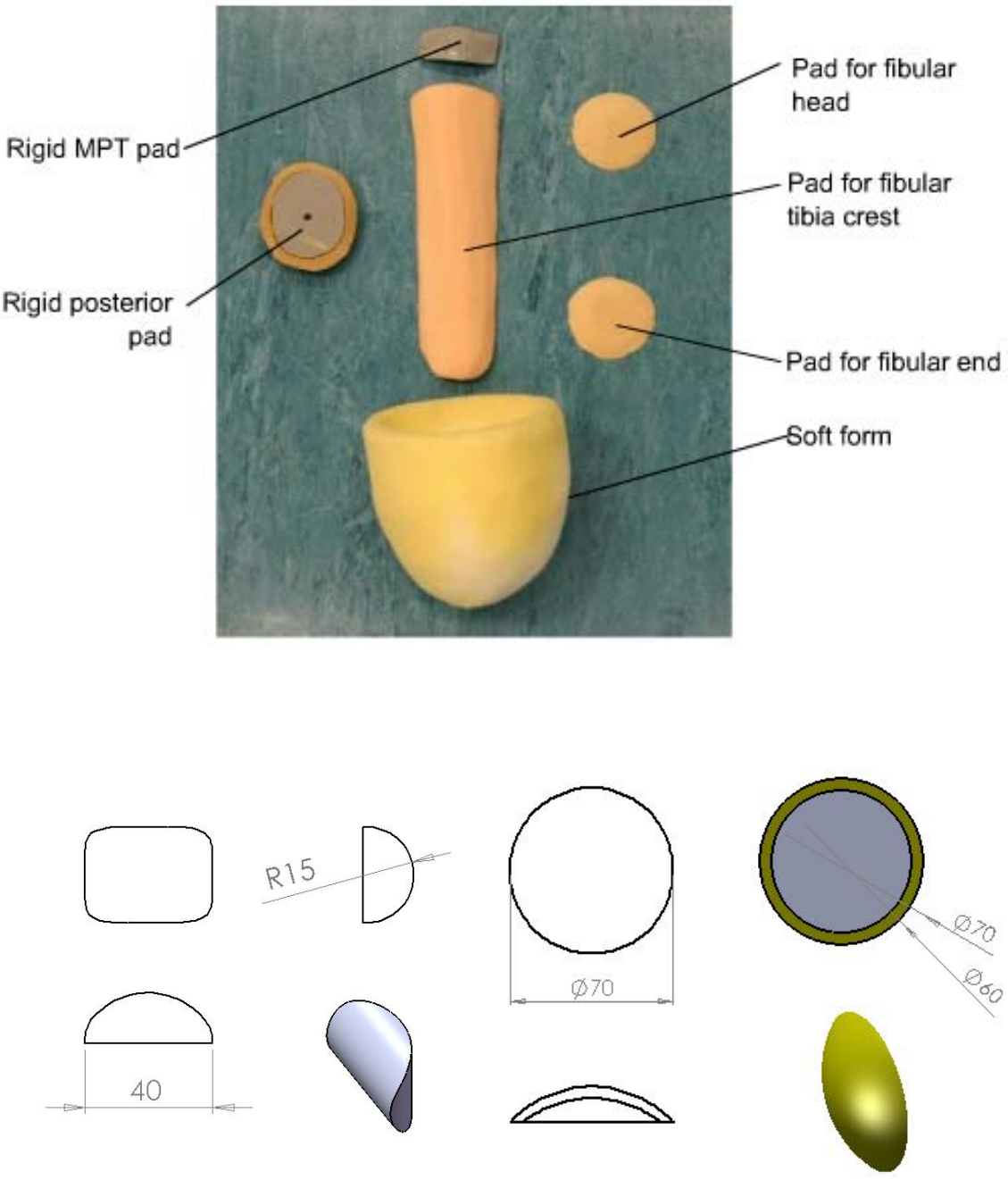
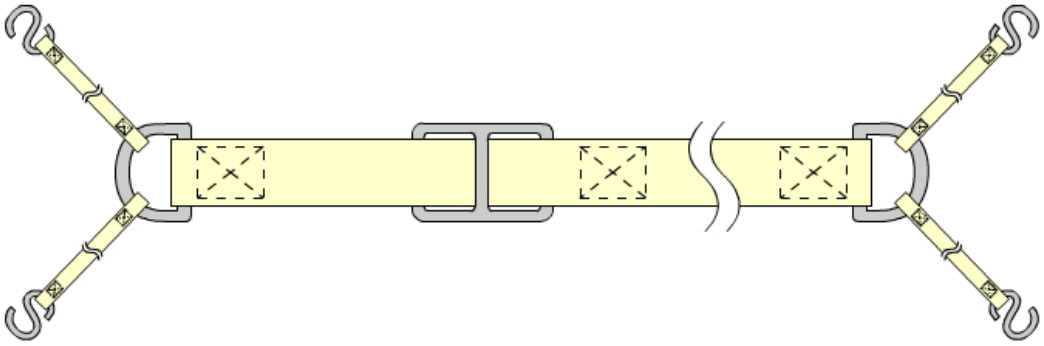
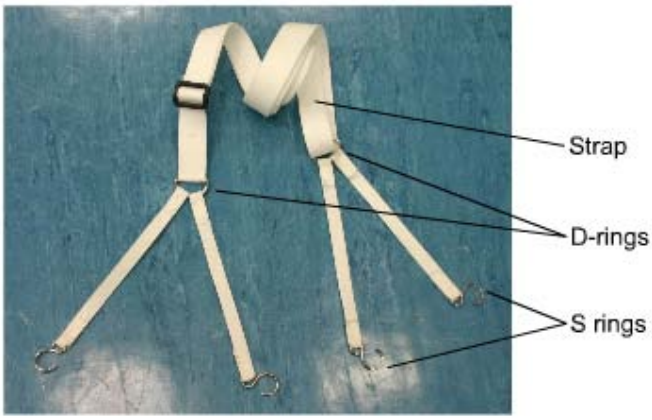
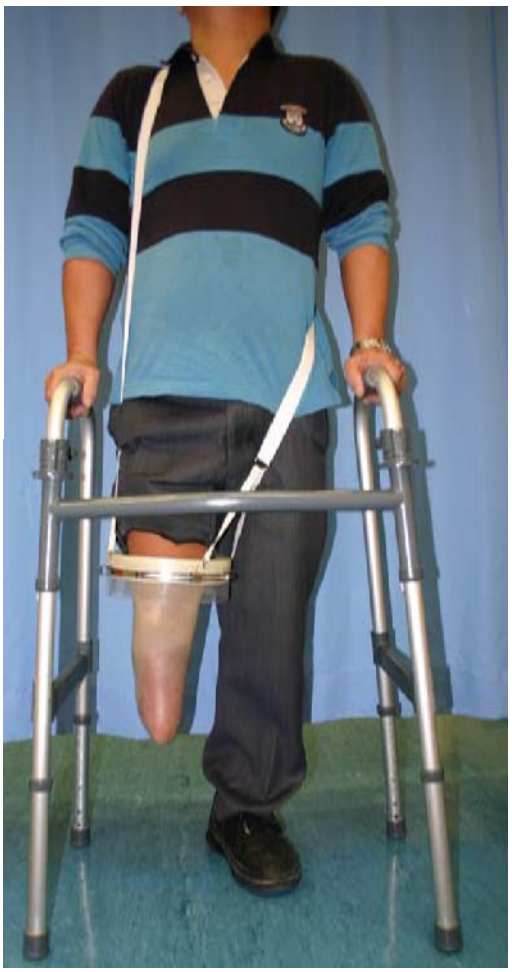


Figure A5. Pelite pads for tibia crest and end of fibule are provide thickening material for weight relieves. The MPT and posterior pads are made of rigid material, such as PVA, to made indentations on the soft tissue region.

A6. Latex cap suspension belt







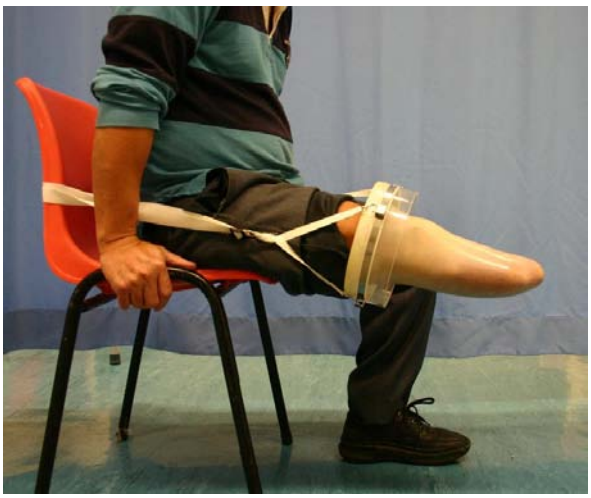
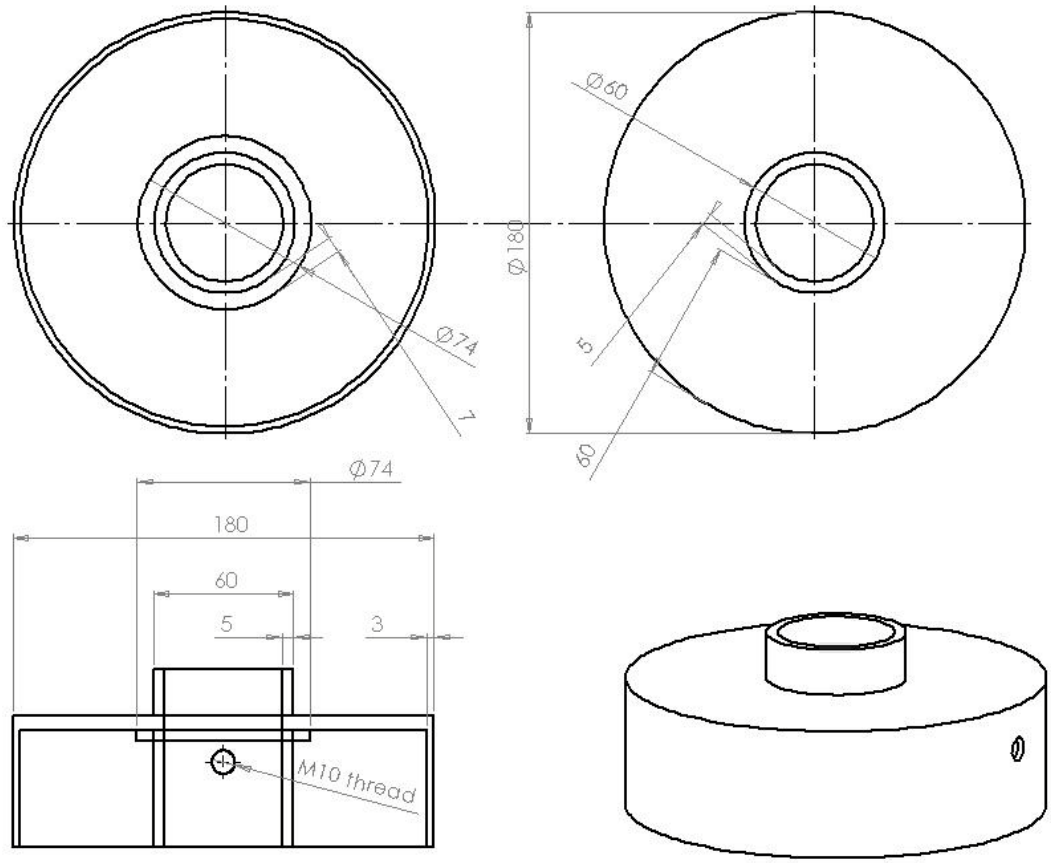


Figure A6. The suspension belt fixes the acrylic ring against recoil force of latex cap in sitting and standing position.

A7. Vacuum cap



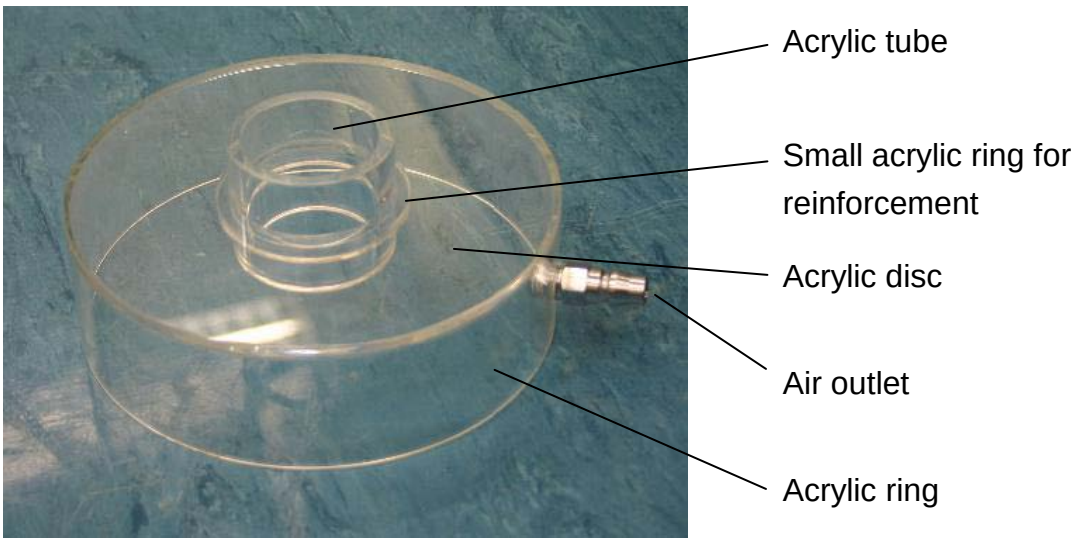


Figure A7. The vacuum cap is designed for second vacuum.

A8. Casting mandrel

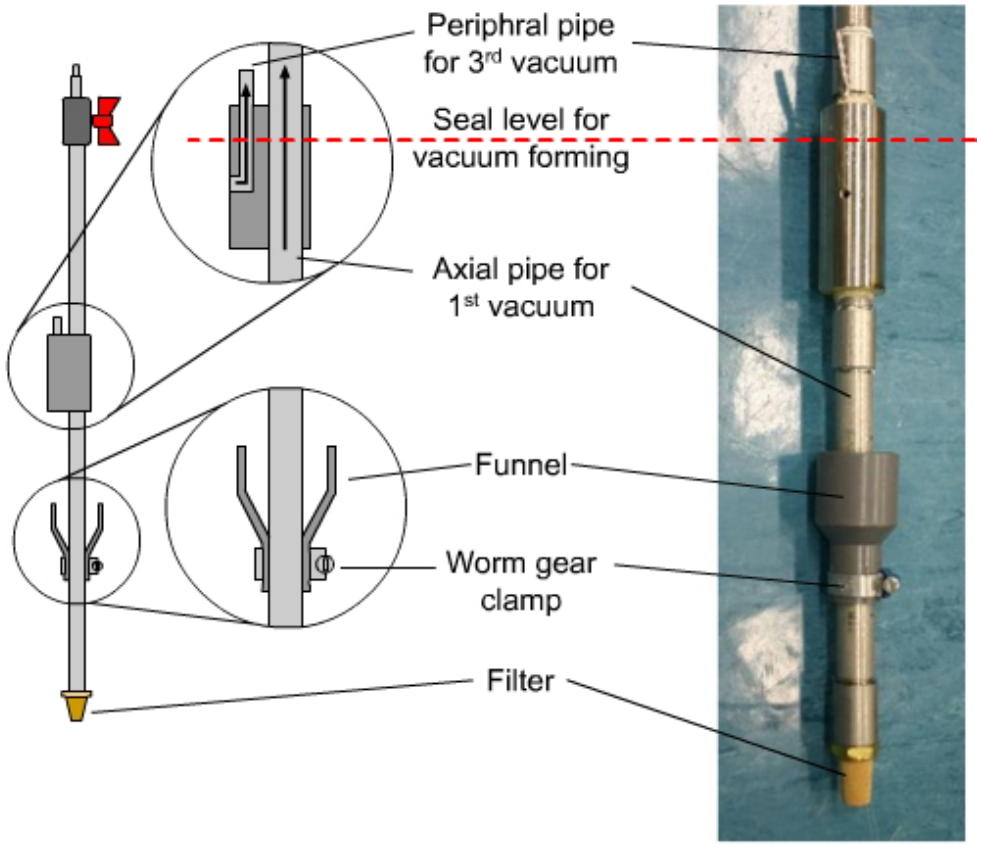


Figure A8. The middle part of casting mandrel consists of 3 metal tubes. The outer largest metal tube embraces the axial and L-shaped air pipes for first and second vacuum processes respectively. The connection of the tubes can be achieved by plaster or polyurethane foam available in prosthesis workshop. The funnel and filter are off-the shelf products for water pipe connection and noise reduction in pressurized gas systems respectively.

A9. Casting rod

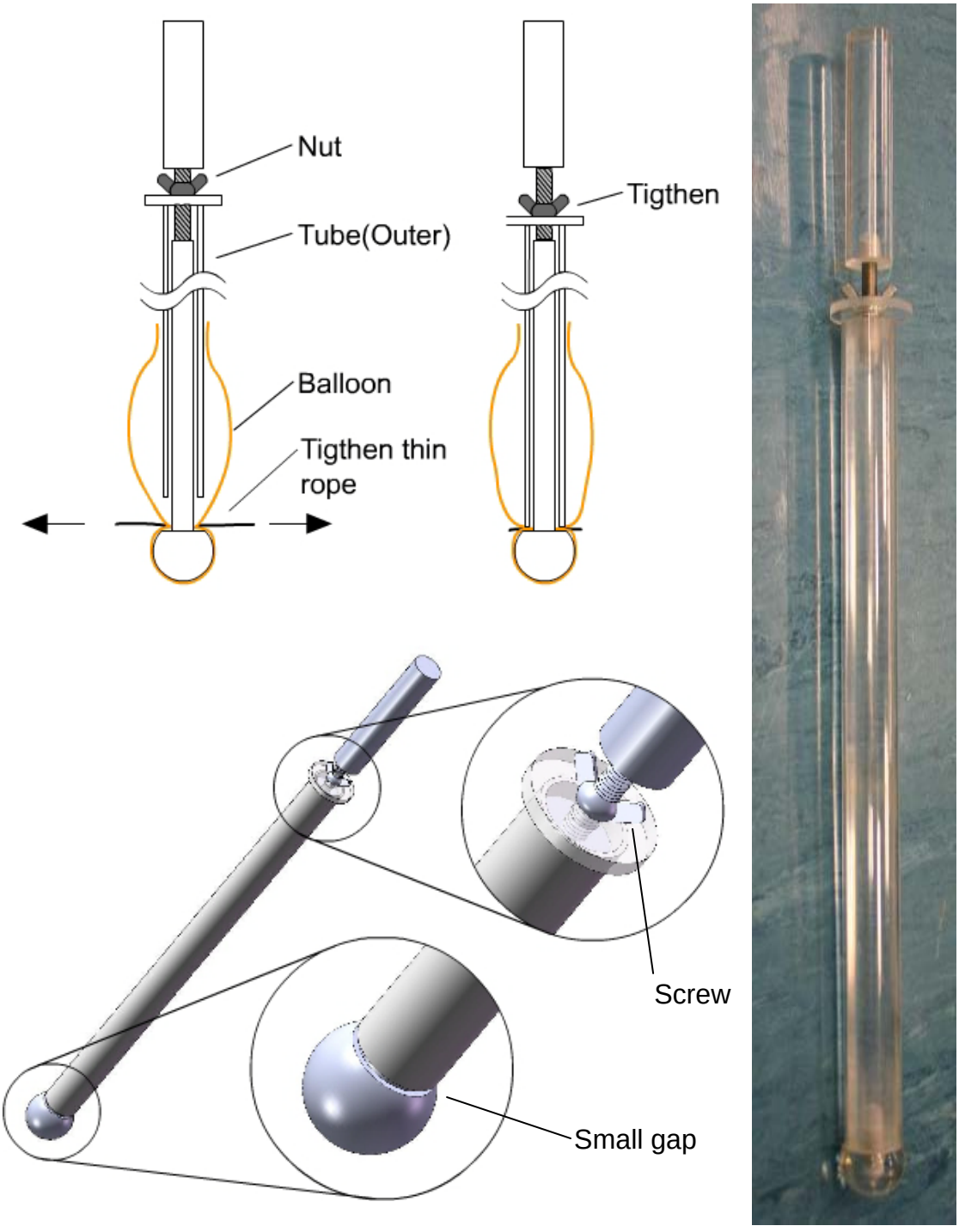
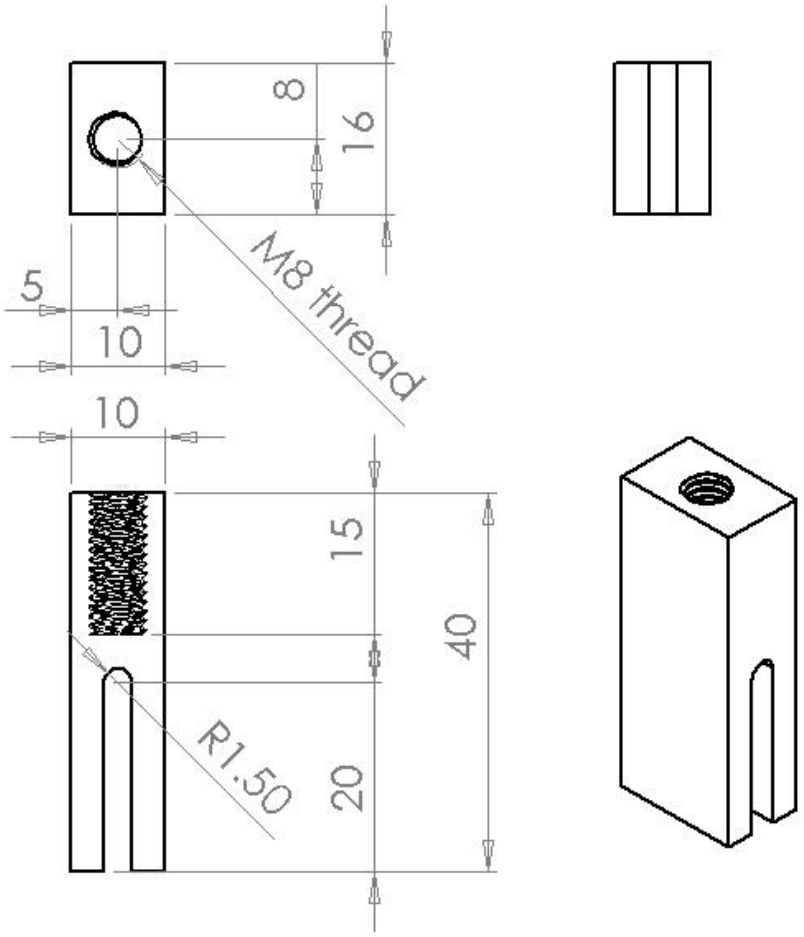


Figure A9. A small gap between the spherical head and the hollow tube is controlled by the screw to grasp and release the latex cap.

A10. Tube-screw connector



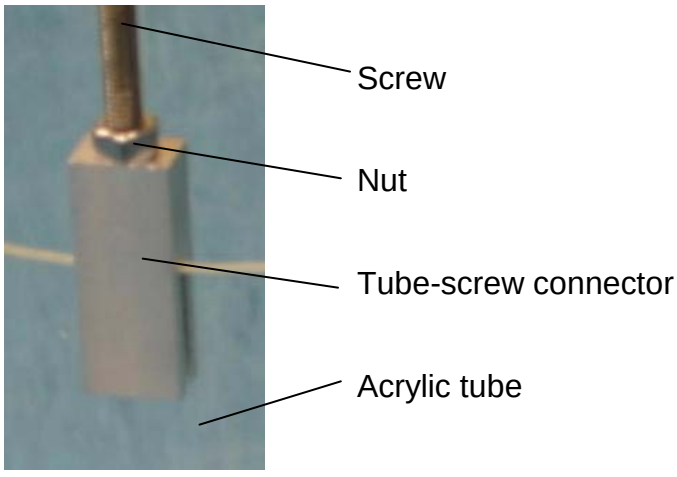
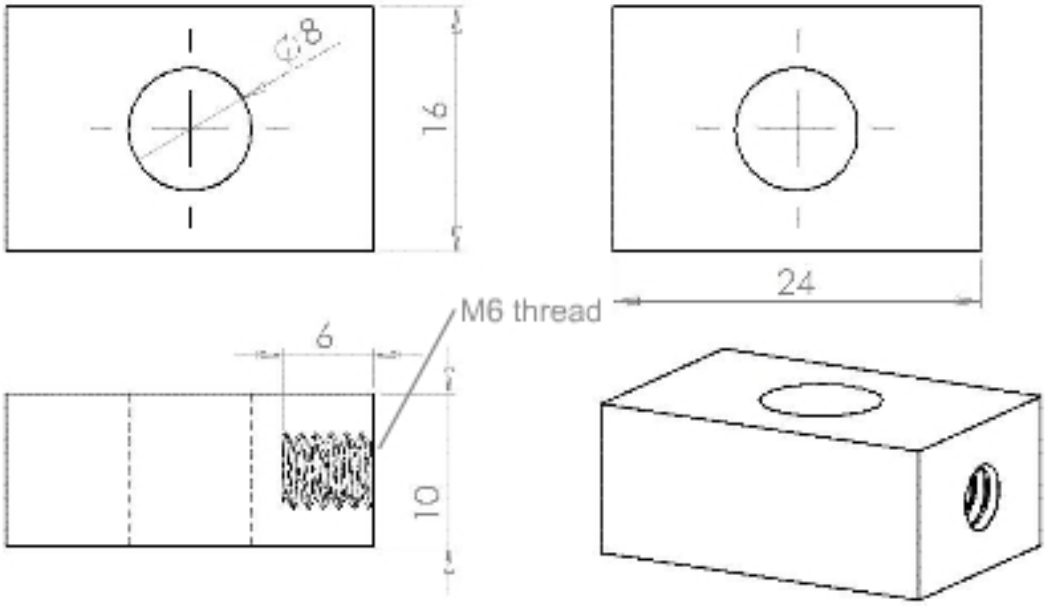


Figure A10 Tube-screw connector provides a platform for vertical screw attaching on the edge of acrylic tube.

A11. Level adjustment knob



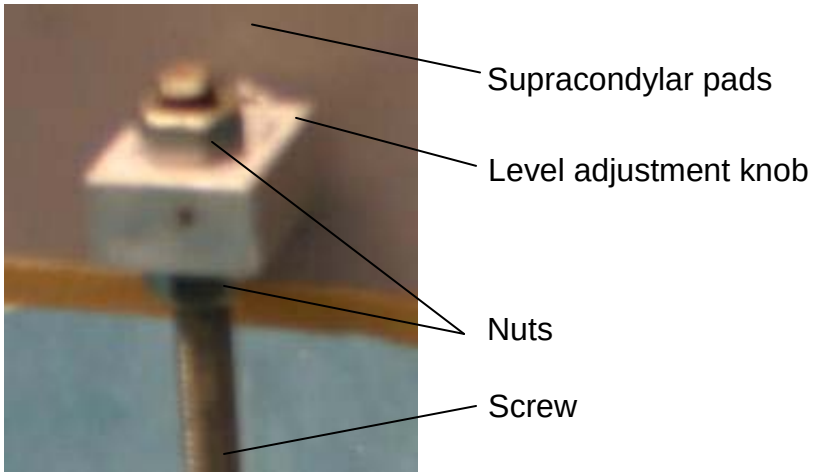
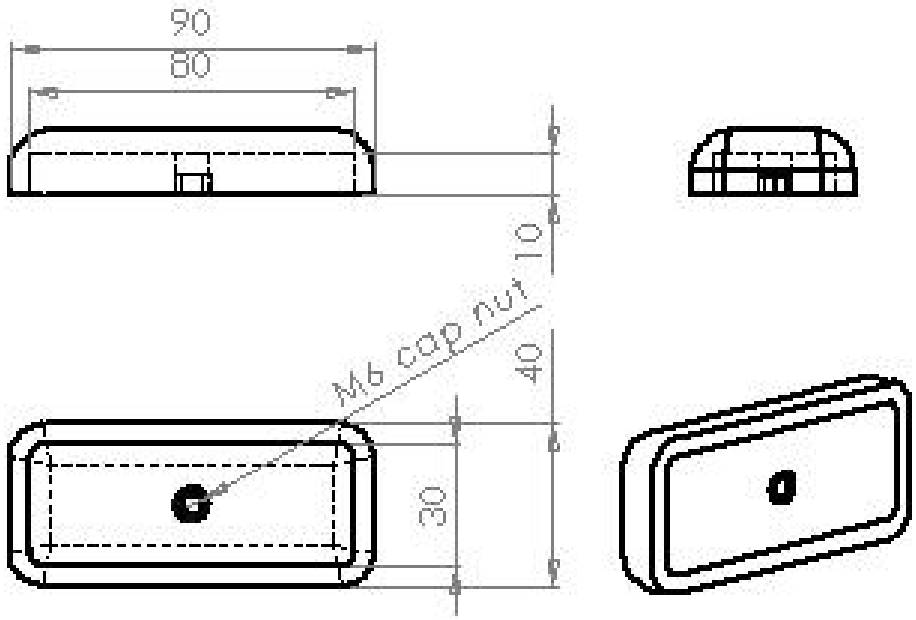


Figure A11. Level adjustment knob connects the supracondylar pads on vertical screw and it is fixed by a pair of nuts.

A12. Supracondylar pads



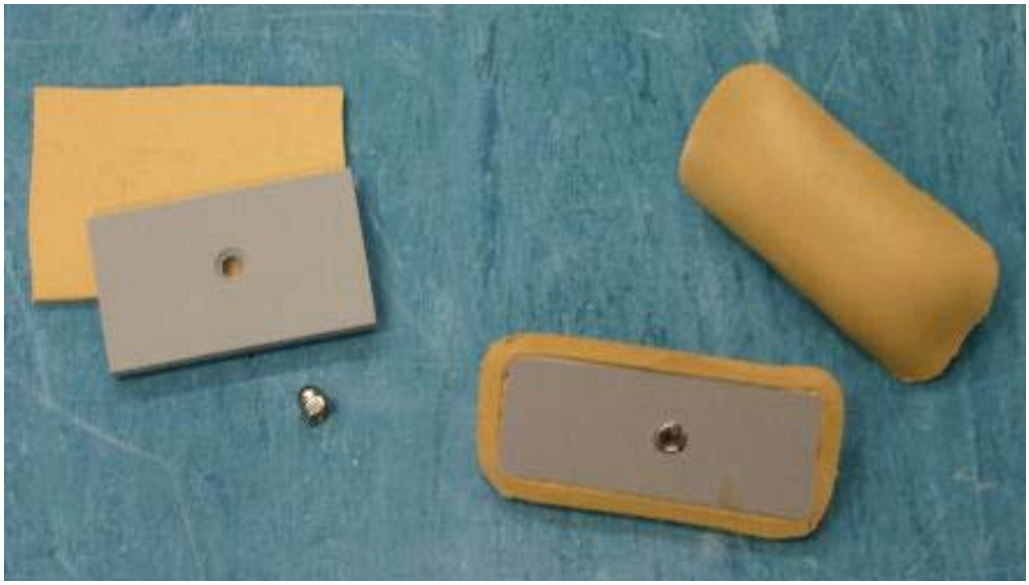


Figure A12. Custom-made supracondylar pad comprised of soft liner, rigid plastic plate attaching a M6 cap nut in the center. The pad on the lateral side of temporary prosthesis is flat in shape, whereas the medial one is convex for indentation.

A13. Antennas and pad for supracondylar suspension

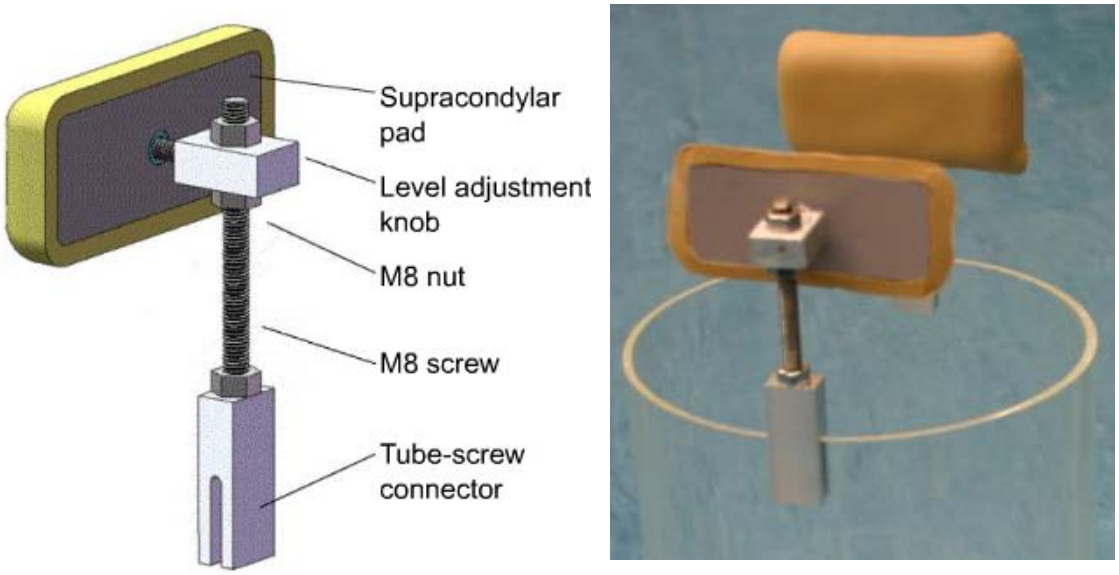


Figure A13 It consists of supracondylar pad, tube-screw connector and level adjustment knob connected by screws.

A14. Vacuum forming mandrel

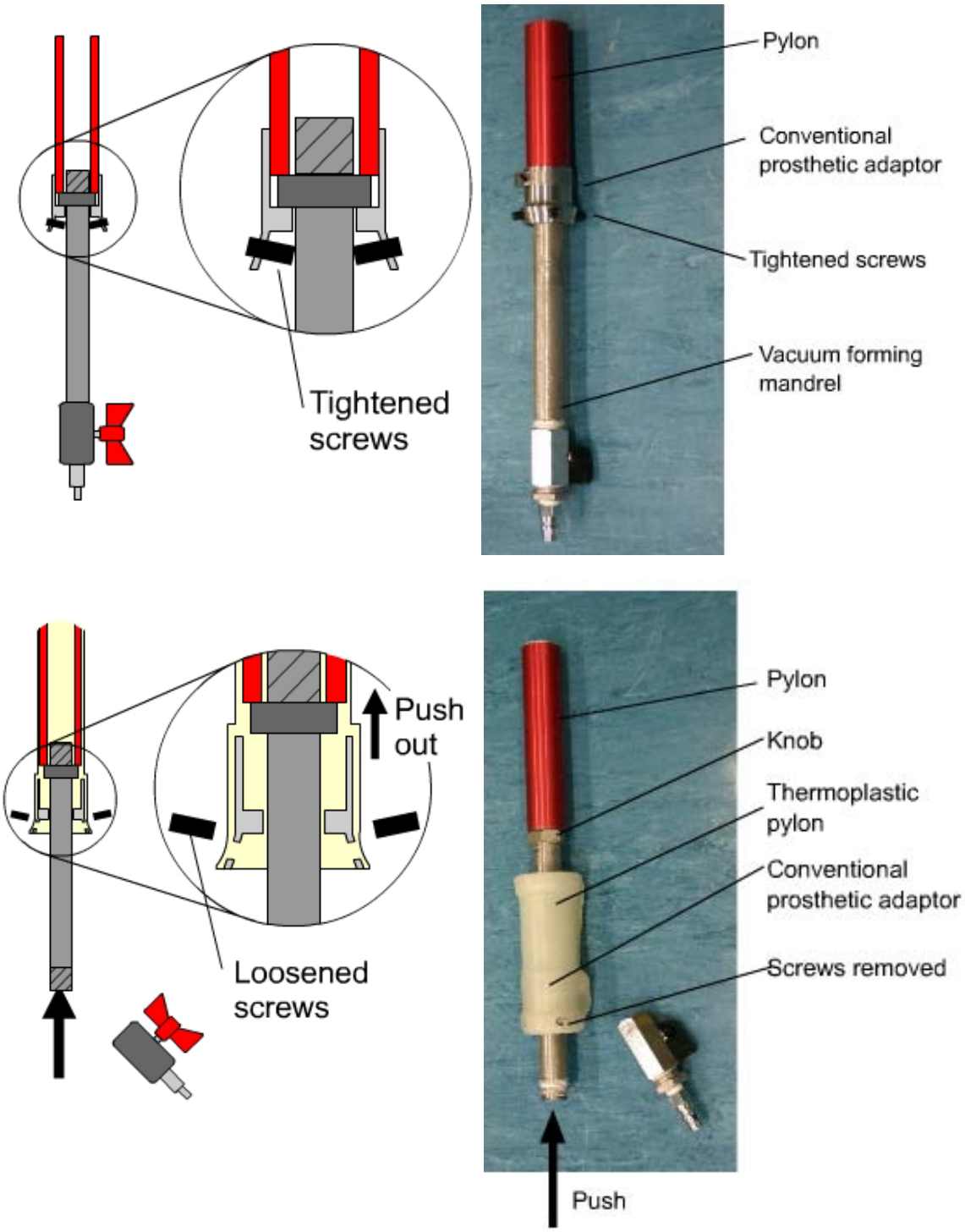


Figure A14 Pylon is pushed away from monolimb by hitting the end of vacuum foaming mandrel.

A15. Alignment jig

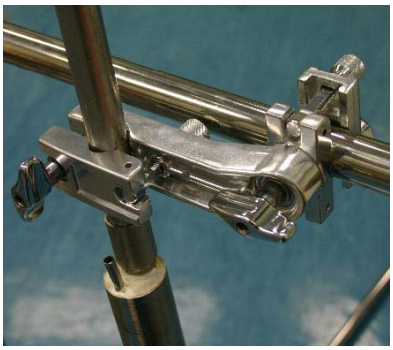
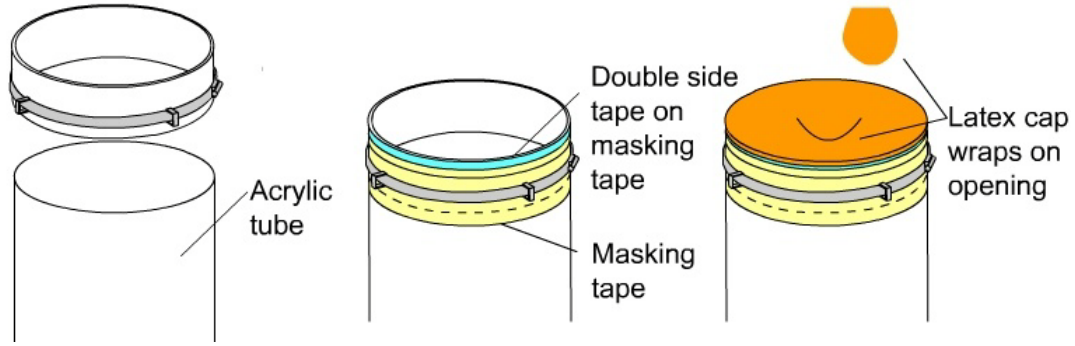


Figure A15. The alignment jig may be simply a rectangular metal frame comprised of common metal rods and joints. The structure can be dismantled and assemble for transportation. The casting and vacuum forming mandrels fix on alignment jig with metal clamp which is available in musical instrument store as a common connector for drum set.

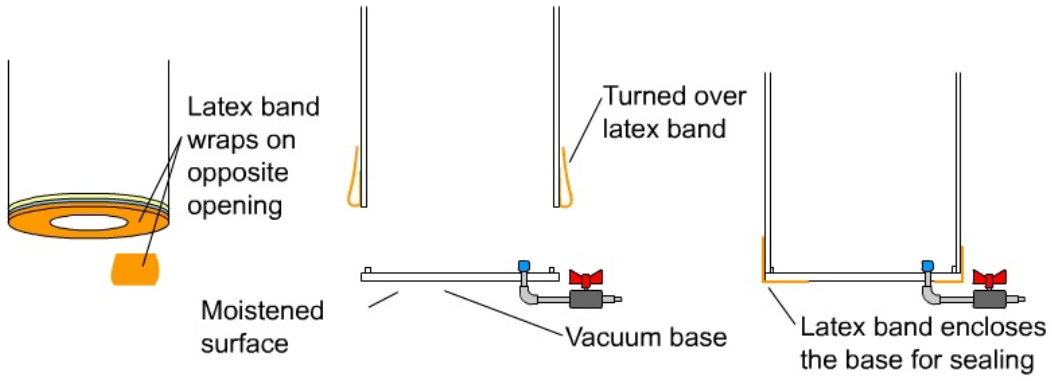
APPENDIX B Procedures of Modified Dilatancy Casting and Vacuum Forming for Monolimb Fabrication

B1 Sealing the end of Casting Cylinder with Latex Membrane



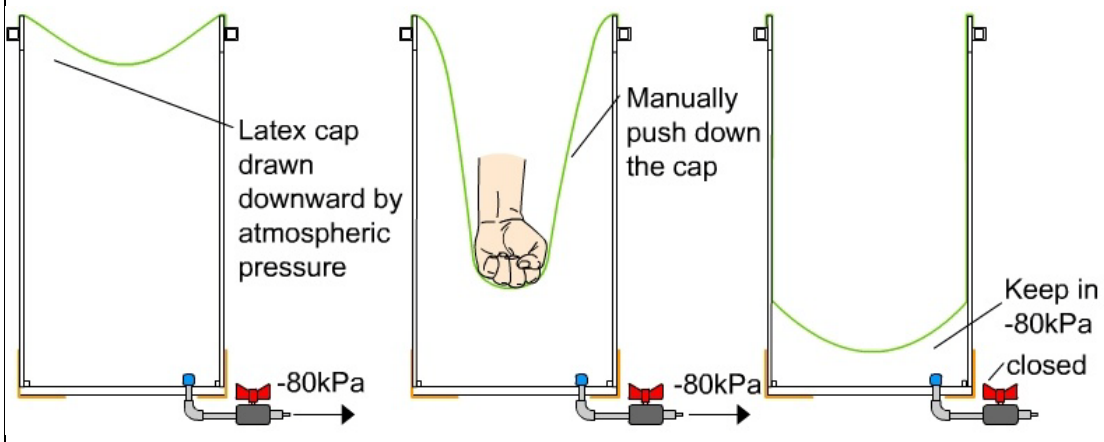
Put four square-shaped short rings into a worm gear clamp and hence fasten the clamp on an acrylic ring with 20cm in diameter and 5cm in height (Appendix A3). Connect the acrylic ring to an acrylic tube with 70cm in length and same diameter with masking tape. Stick a masking tape and then double-side tape around an acrylic ring. Wrap a latex cap on the ring so that 1cm of the cap is sticking around the ring (Appendix A4).

B2 Sealing another End of the Casting Cylinder with Vacuum Base and Latex Band



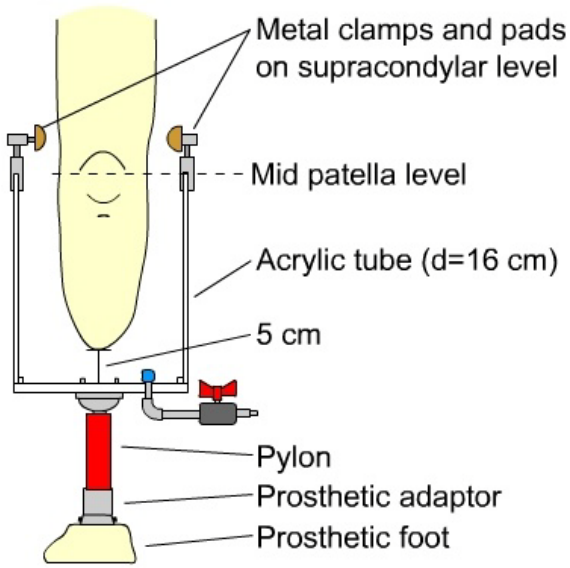
Put a masking tape and then double-side tape around the other end of acrylic tube. Similar to previous procedure, wrap latex band on the end of the tube to form a ring. Wrap the edge of latex on the tube with masking tape increase the endurance for repeated use (Appendix A4). Turn over the latex extrusion and connect the moistened vacuum base with 20cm diameter (Appendix A1). Encapsulate the base with the extrusion so that the base is fixed on the long acrylic tube. This method provides a simple but effective way to hold a vacuum base on the end of acrylic tube with air sealing feature (Appendix A3).

B3 Elongation of Latex Membrane along the Casting Cylinder



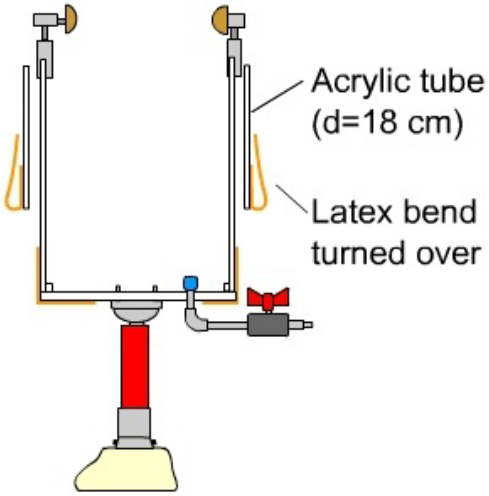
Apply vacuum pressure via the outlet of the base to suck down the latex cap. Manually push down the cap so that it can expand and stretch evenly. Turn off the air outlet and keep the negative pressure in the tube when the cap almost reached the vacuum base (Figure 3.7a). It forms an elongated latex cap fast and easily to let the latex cap put on residual limb evenly.

B4 Determine Lengths of Temporary Prosthetic Components



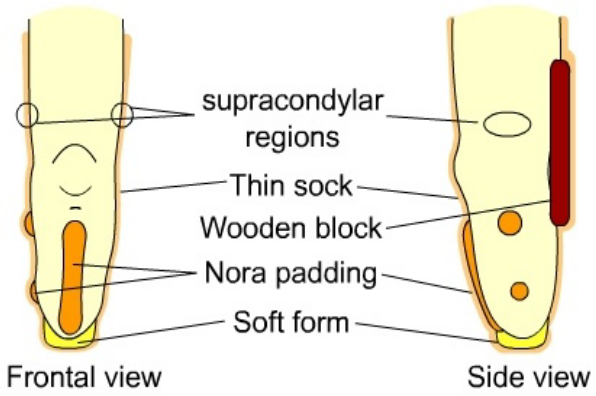
Connect the traditional prosthetic foot, pylon and connectors to a small vacuum base (Appendix A2). The distal end of residual limb is above the base by 5cm in standing position. Put a thin acrylic tube on the base so that the top of the tube reaches the mid patella level. Fix antennas and pads on both medial and lateral sides of the top of the thin tube to determine the suitable length of the screws (Appendix A10-A13).

B5 Preparations for Upper Casting Cylinder



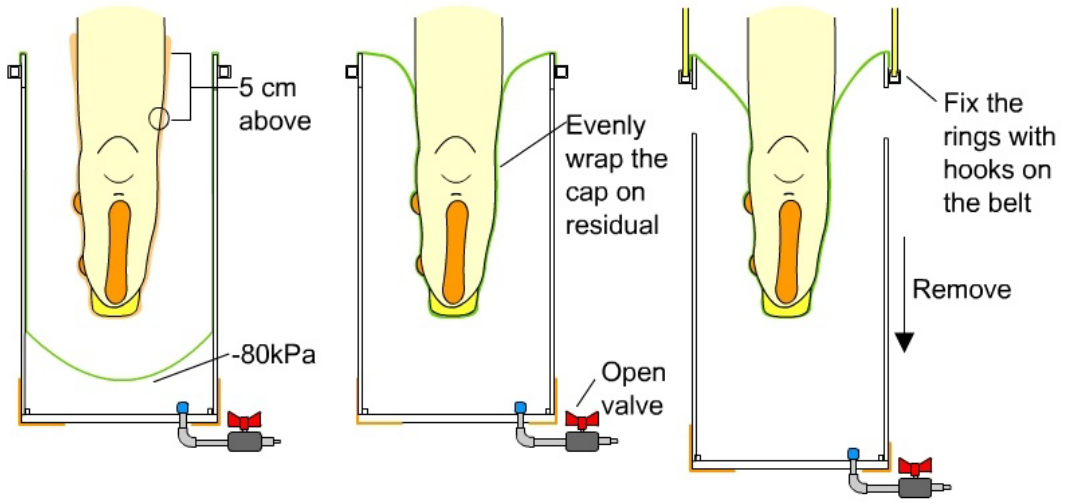
After the lengths of pylon, thin acrylic tube and the screws are confirmed, connect the tube with a vacuum base (small) as described in section B1 (Appendix A4). Masking tape and double side tape are wrapped around the both ends of thicker acrylic tube with 18cm in diameter. Wrap a latex band on the lower end of the tube and put it on the thin tube.

B6 Soft Pad on Sensitive Regions of Residual Limb for Pressure Relieves



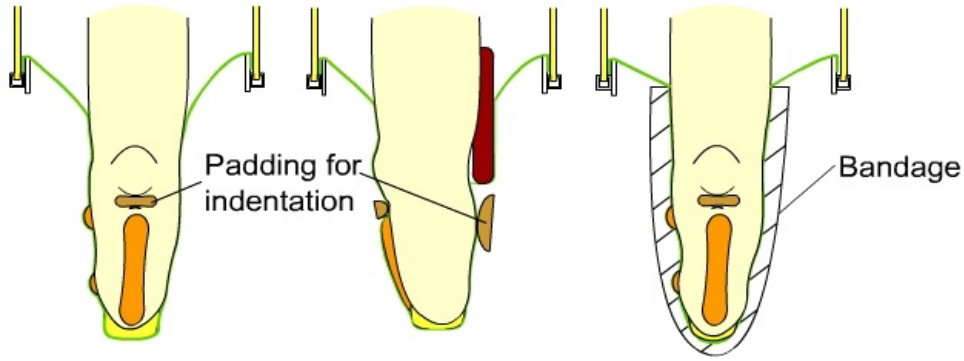
Stick soft pads and a soft form cap with micropore tape on bony prominent regions and distal end of the stump respectively (Appendix A5). Stick a rounded edge wooden block coated with thin socks with 2cm in thickness on the posterior region to form the shape of posterior brim. Put a thin sock on the residual limb.

B7 Donning Latex Cap on Residual Limb



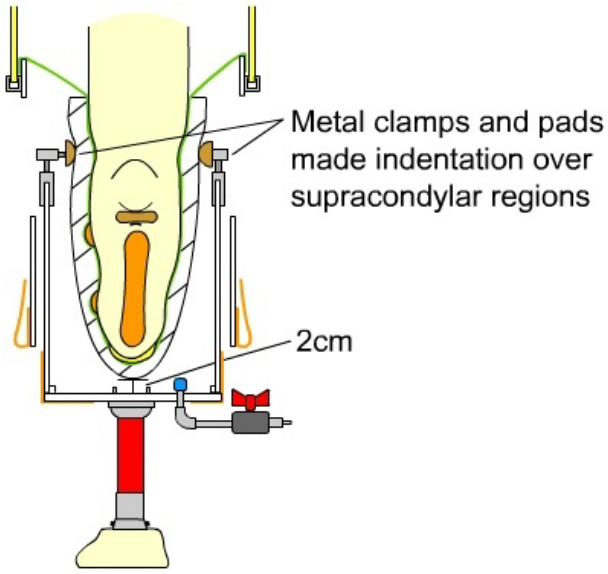
Insert residual limb into the cavity until the supracondylar level of knee is under the opening by 5cm. Equalize the air pressure in the cylinder and let cap retracts upward and wraps evenly on the residual. Put the hooks of the belt on the square shape rings fixed on the worm gear clamp to fix the position. Disconnect the acrylic tube and base (Appendix A6).

B8 Wrapping Bandage on Residual Limb



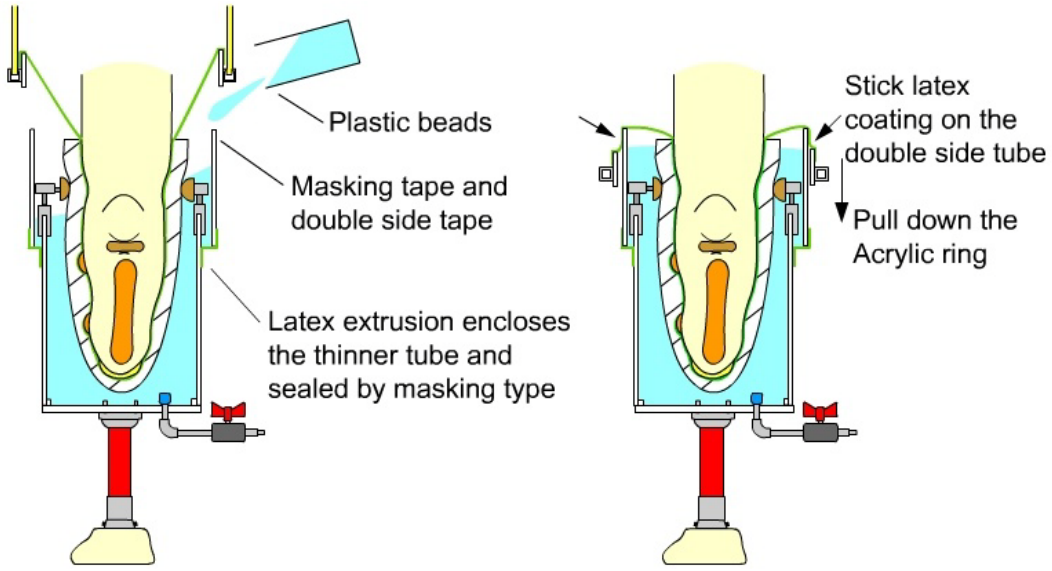
Stick indentation pads (Appendix A5) on the mid-patella and posterior regions and wrap a bandage on the residual limb firmly in order to push the pads towards the soft tissue to make indentations. The bandage also squeezes the stump to be slimmer and longer in shape.

B9 Fix the Casting Cylinder on Residual Limb with Supracondylar Cushion



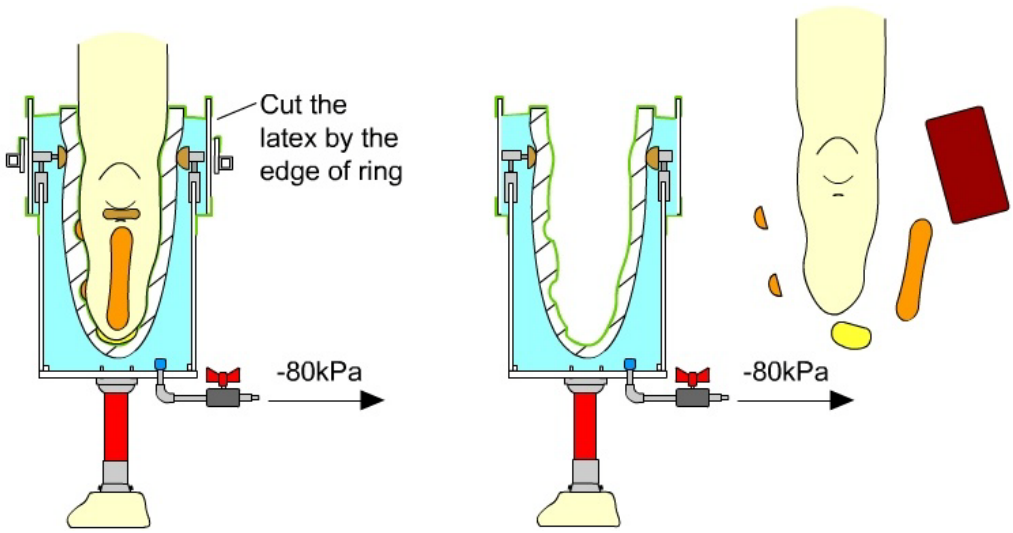
Put the temporary prosthesis on the distal limb. The distal end of residual limb is above the base by 2cm in standing position. Adjust the horizontal screws on supracondylar regions so that temporary prosthesis is not only located firm enough to suspense on the residual, but also can be manually put off. Keep the standing position with the walking aim. Observe the positions of residual limb relative to the pylon in front and side views to adjust the static alignment.

B10 Fill the Casting Cylinders with Plastic Beads and Sealing



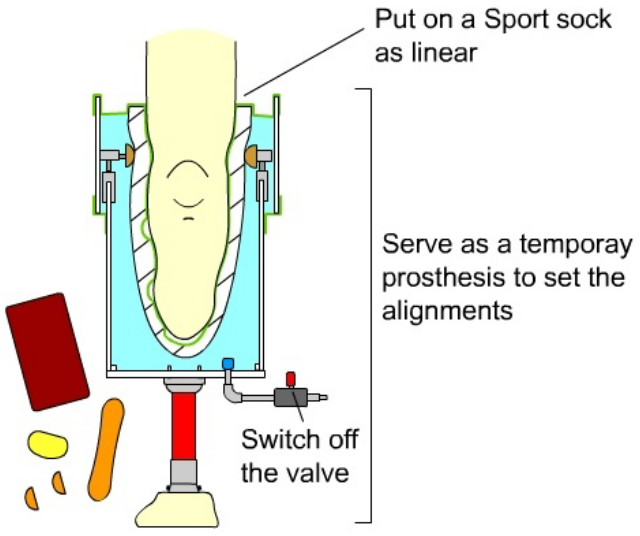
Keep the position of residual limb and move the middle tube upwards until the top of tube is above the cushions by 2cm. Turn over the latex band at the end of outer tube and then wrap it on the thinner acrylic tube. Seal the gap with masking tape. Fill the plastic beads to the acrylic tubes with gentle shaking to pack the beads denser. Once the beads filled over the cushion pads, the subject can stand without the aim of tetapod. Remove the hooks on the square shaped rings and carefully descend the thickest outer acrylic tube so that the latex coating is stacked on the double side tape on the upper end of 18cm middle tube to seal the cavity.

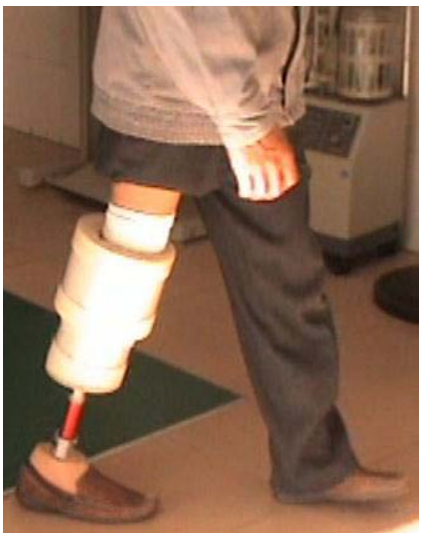
B11 First Vacuum to Form Temporary Prosthesis



Cut the latex coating by the edge of outer acrylic tube for detachment. After the subject is standing on the container with well alignment, apply vacuum pressure via the base to form the immediate prosthesis. Withdrawn the wooden block and hence the stump from the harden impression. Remove all the pads stuck on the stump.

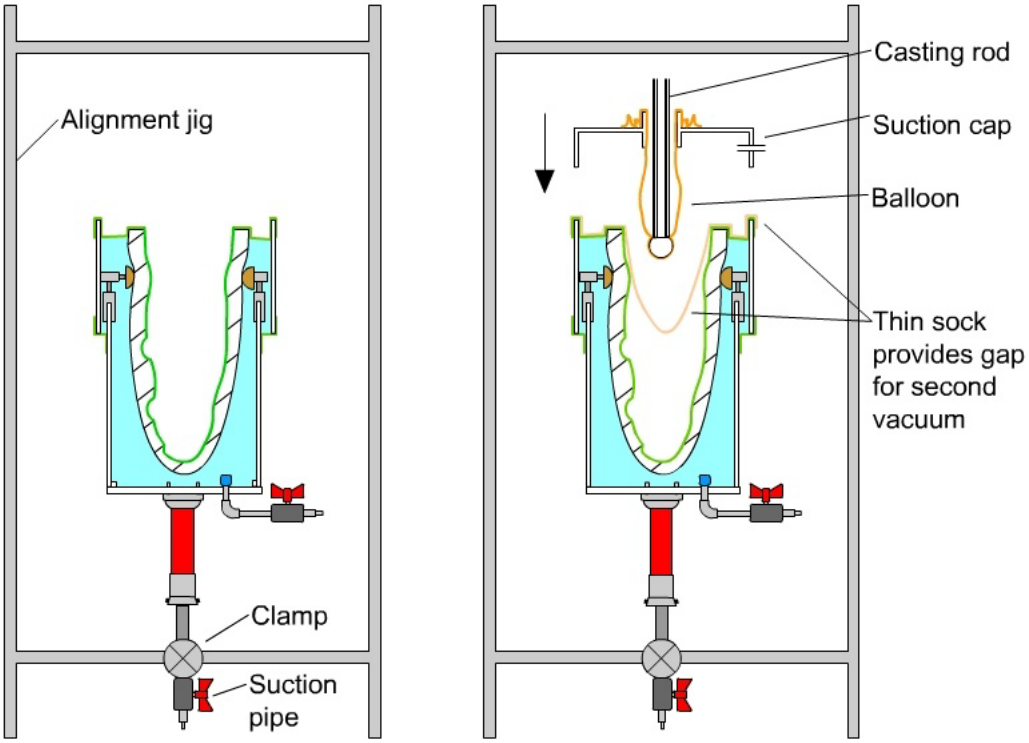
B12 Static and Dynamic Alignment of Temporary Prosthesis





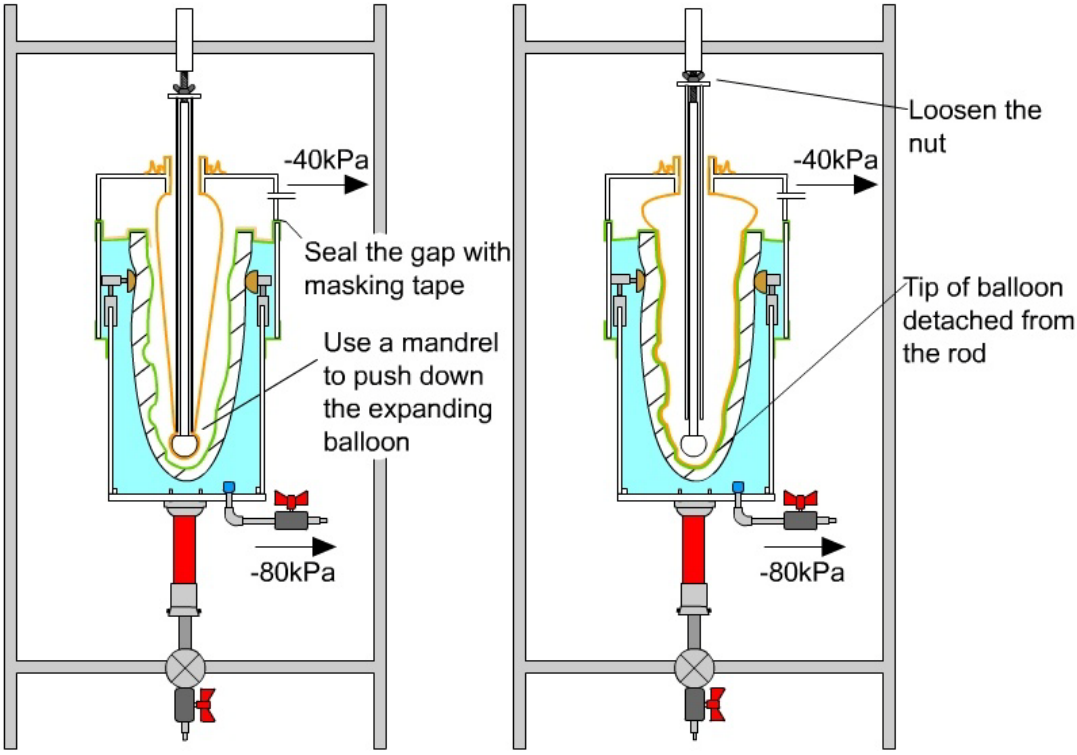
Put one to two pieces of sports sock on the residual limb and try the immediate prostheses. Close the valve on the base and disconnect the prosthesis from the vacuum bump. Check static, dynamic alignments and the height of the prosthesis. Adjust the adaptors on both ends of pylon and to obtain the desirable alignments.

B13 Fix the Temporary Prosthesis on Alignment Jig



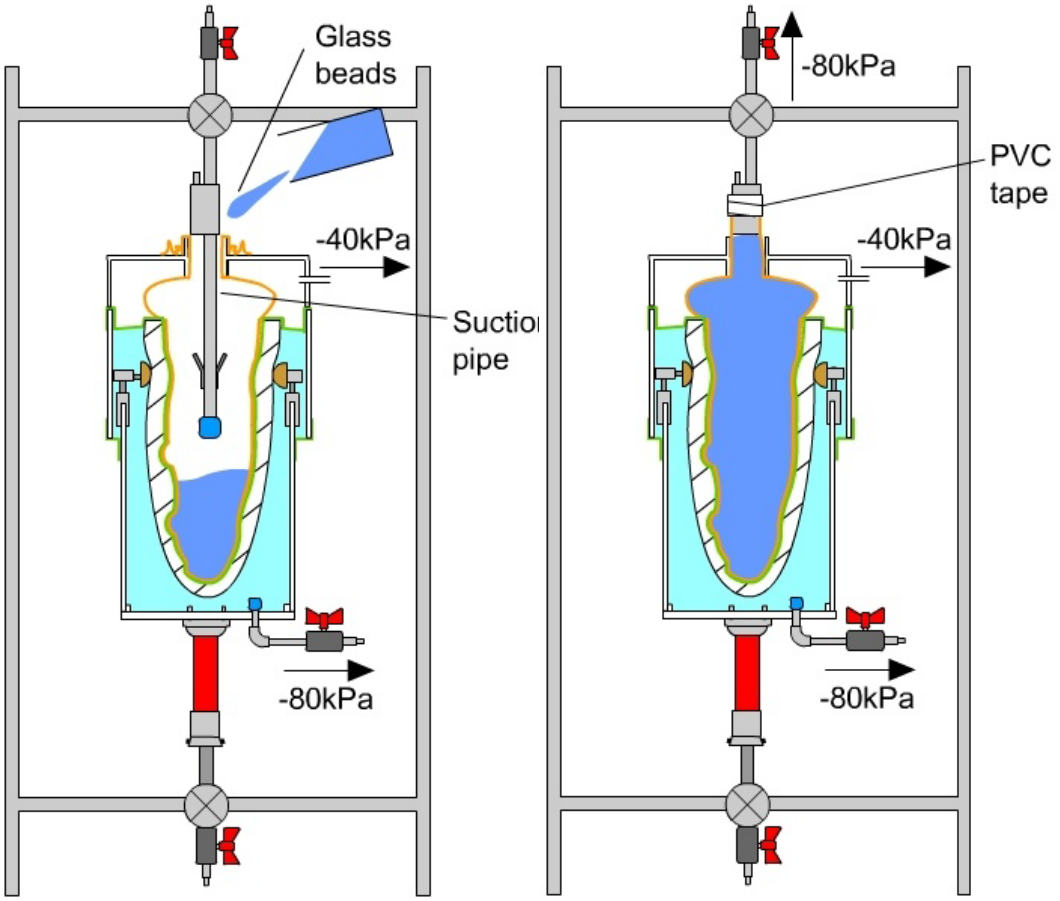
Detach the prosthetic foot and fix a vacuum forming mandrel on the distal prosthetic adaptor (Appendix A14). Clamp the pipe on the alignment jig firmly (Appendix A15). Wrap a thin sock on the top of immediate prosthesis by additional double side tape to provide a gap for second vacuum. Put a latex balloon on the casting rod and wrap the neck of the balloon on the mouth of vacuum cap (Appendix A7 and A9). Connect the vacuum cap on the top and seal the gap by masking tape.

B14 Second Vacuum to lay Casting Balloon on Impression



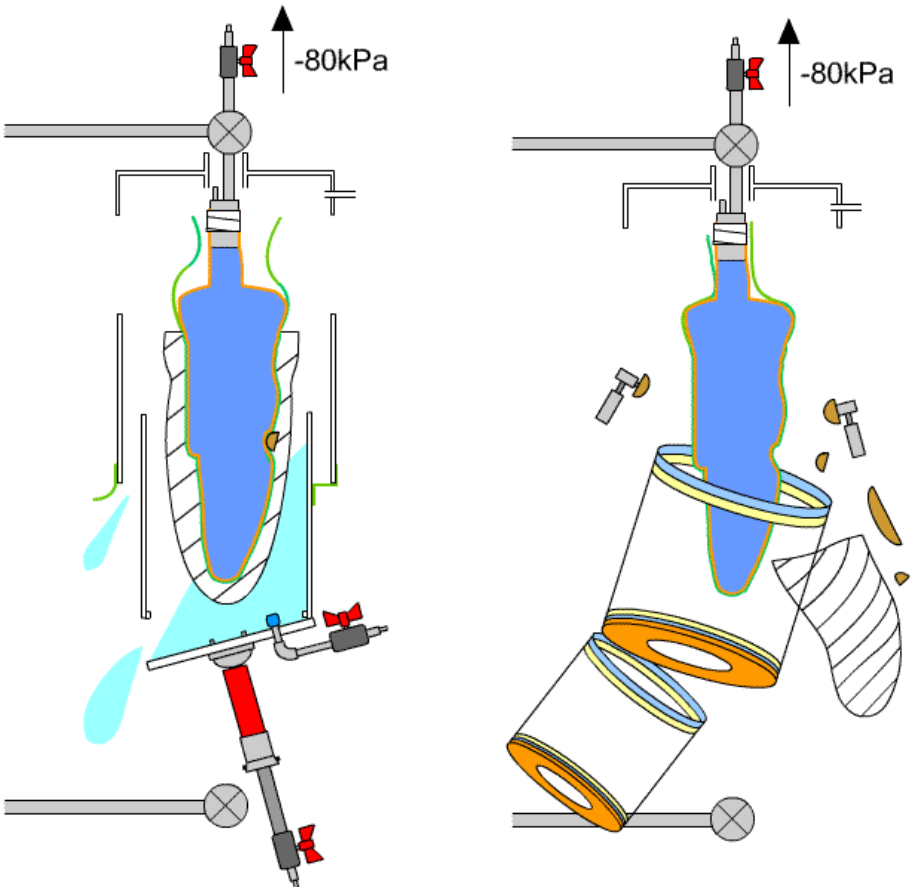
Maintain the negative pressure in the prosthesis about -80kPa. Apply second vacuum via the outlet of the vacuum cap to reduce the pressure between the cap and the impression to -40kPa (Since the shape or hardness of impression is maintained by pressure gradient). Gently push the casting rod downward while the balloon is expanding. Loosen the nut of the rod to loosen the balloon when the latex balloon completely inflated and lie on the inner wall of impression.

B15 Third Vacuum to form Sand Cast Residual Limb Model



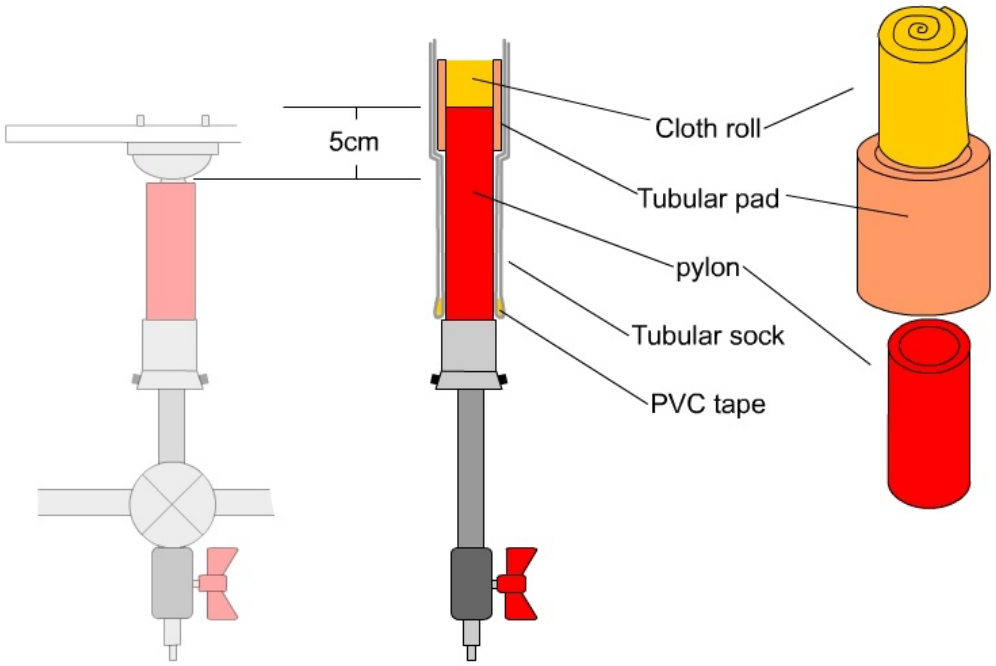
Remove the casting rod and insert the suction mandrel thought the vacuum cap. Clamp the mandrel on the alignment jig while it does not contact the socket wall. Fill glass beads to the cavity of immediate prosthesis. Wrap the mouth of balloon upward onto the mandrel to seal the beads with PVC tape. Apply vacuum pressure of -80kPa via the mandrel to form a hard model. Disconnect the vacuum cap and the air outlet of the vacuum base from the pump (Appendix A8).

B16 Temporary Prosthesis Removal



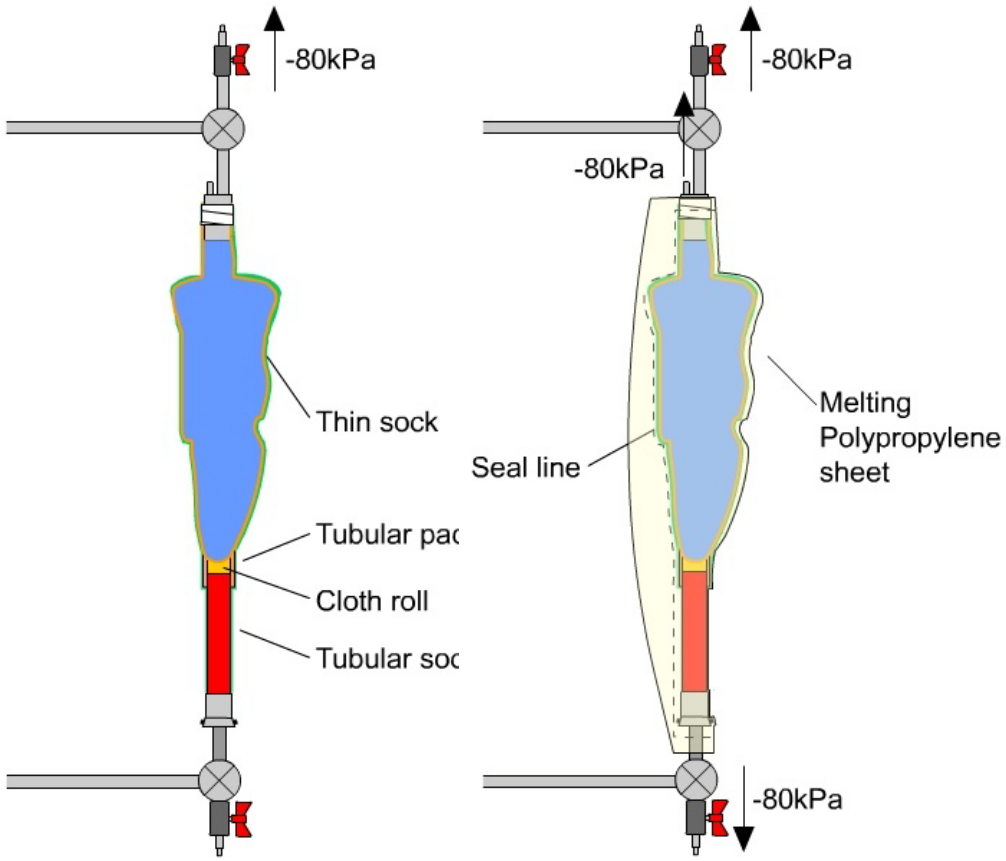
Remove the vacuum cap and the latex cap stuck on the top of upper acrylic tube. Turn over the latex band and disconnect the acrylic tube from the inner one. Mark the position of vacuum forming mandrel relative to the alignment jig and remove it together with the vacuum base to collect the reusable plastic beads. Remove the bandages and pads pressing on the supracondylar regions.

B17 Dummy Prosthetic Connector



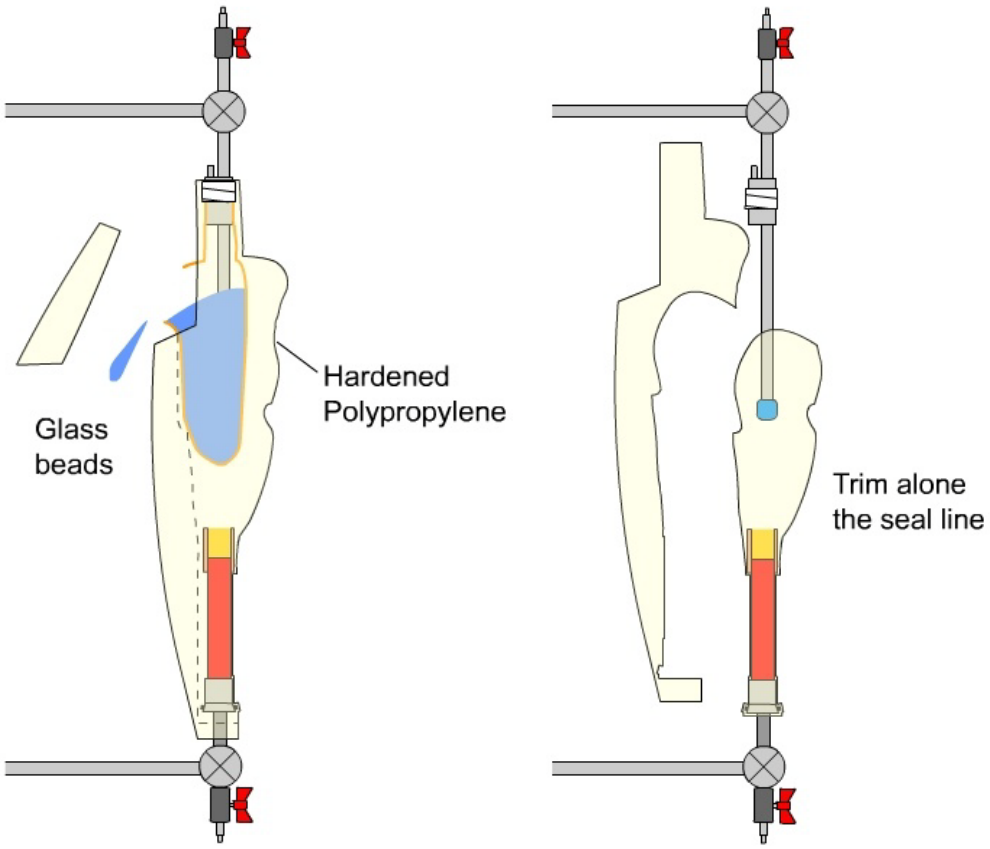
Replace the pylon, with longer than original by about 5cm, on the vacuum forming mandrel. Place a soft tubular pad with 5cm on the top of the pylon. Fill the center of the tubular pad with a roll of cloth. Put a thin tubular sock on the pad and pylon. Hold the sock in position by wrapping PVC tape just above the prosthetic adaptor; hence fold the sock upward so that the pylon and the pad are covered by double layers of the tubular sock.

B18 Thermoplastic Vacuum Forming of Monolimb



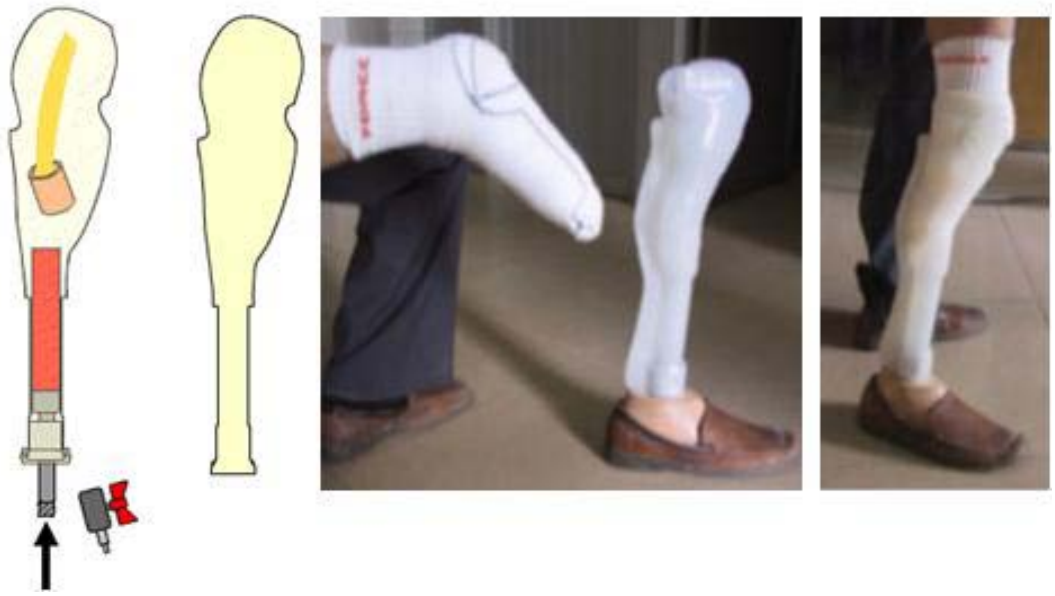
Put a thin sock on the model for the thermoplastic vacuum forming. Connect a vacuum forming mandrel and related components on the alignment jig. Mould a 5mm softened polypropylene sheet on the set. Connect the peripheral air outlets of suction mandrel (Appendix A8) and vacuum forming mandrel and to vacuum pump and form the shape of monolimb by the means of vacuum forming method. **Note: Do not stretch the thermoplastic during vacuum forming to avoid the wall of monolimb being too thin and fail to support body weight.**

B19 Demoulding of Sand Casting Monolimb



After the polypropylene cool down completely, drill a hole above the posterior brim region to collect the reusable glass beads. Trim alone the seal line to get the prosthesis.

B20 Remove Prosthetic Pylon and Dummy Connector for Finish



Remove the cloth and tubular soft liner, loosen the screws on the prosthetic adaptor. Pull the pylon out by hammering the end of vacuum forming mandrel (Appendix A14). The monolimb is completed after polishing.

APPENDIXC Questionnaire

Amputee Mobility Predictor Questionaire

Initial instructions:

Testee is seated in a hard chair with arms. The following maneuvers are tested with or without the use of the prosthesis. Advise the person of each task or group of tasks prior to performance. Please avoid unnecessary chatter throughout the test. Safety first, no task should be performed if either the tester or testee is uncertain of a safe outcome.

The Right Limb is: ❒ PF ❒ TT ❒ KD ❒ TF ❒ HD ❒ intact. The Left Limb is: ❒ PF ❒ TT ❒ KD ❒ TF ❒ HD ❒ intact.

1. Sitting balance: sit forward in a chair with arms folded across chest for 60s.	Cannot sit upright independently for 60s Can sit upright independently for 60s	=0 =1	_____
2. Sitting reach: reach forward and grasp the ruler. (Tester holds ruler 12in beyond extended arms midline to the sternum.)	Does not attempt Cannot grasp or requires arm support Reaches forward and successfully grasps item	=0 =1 =2	_____
3. Chair to chair transfer: 2 chairs at 90°. Pt may choose direction and use their upper extremities.	Cannot do or requires physical assistance Performs independently, but appears unsteady Performs independently, appears to be steady and safe	=0 =1 =2	_____
4. Arises from a chair: ask pt to fold arms across chest and stand. If unable, use arms or assistive device.	Unable without help (physical assistance) Able, uses arms/assist device to help Able, without using arms	=0 =1 =2	_____
5. Attempts to arise from a chair (stopwatch ready): if attempt in no. 4 was without arms then ignore and allow another attempts without penalty.	Unable without help (physical assistance) Able requires >1 attempt Able to rise 1 attempt	=0 =1 =2	_____
6. Immediate standing balance (first 5s): begin timing immediately.	Unsteady (staggers, moves foot, sways) Steady using walking aid or other support Steady without walker or other support	=0 =1 =2	_____
7. Standing balance (30s) (stopwatch ready): For items nos. 7 & 8, first attempt is without assistive device. If support is required, allow after first attempt.	Unsteady Steady but uses walking aid or other support Standing without support	=0 =1 =2	_____
8. Single-limb standing balance (stopwatch ready): time the duration of single limb standing on both the sound and prosthetic limb up to 30s. Grade the quality, not the time. Sound side ____ seconds Prosthetic side ____ seconds	Nonprosthetic side Unsteady Steady but uses walking aid or other support for 30s Single-limb standing without support for 30s Prosthetic Side Unsteady Steady but uses walking aid or other support for 30s Single-limb standing without support for 30s	=0 =1 =2 =0 =1 =2	_____ _____
9. Standing reach: reach forward and grasp the ruler. (Tester holds ruler 12in beyond extended arm(s) midline to the sternum.)	Does not attempt Cannot grasp or requires arm support on assistive device Reaches forward and successfully grasps item no support	=0 =1 =2	_____
10. Nudge test (subject at maximum position #7): with feet as close together as possible, examiner pushes firmly on subject's sternum with palm of hand 3 times (toes should rise).	Begins to fall Staggers, grabs, catches self, or uses assistive device Steady	=0 =1 =2	_____
11. Eyes closed (at maximum position #7): if support is required grade as unsteady.	Unsteady or grips assistive device Steady without any use of assistive device	=0 =1	_____
12. Picking up objects off the floor (pick up a pencil off the floor placed midline 12in in front of foot).	Unable to pick up object and return to standing Performs with some help (table, chair, walking aid, etc) Performs independently (without help from object or person)	=0 =1 =2	_____
13. Sitting down: ask pt to fold arms across chest and sit. If unable, use arm or assistive device.	Unsafe (misjudged distance, falls into chair) Uses arms, assistive device, or not a smooth motion Safe, smooth motion	=0 =1 =2	_____
14. Initiation of gait (immediately after told to "go").	Any hesitancy or multiple attempts to start No hesitancy	=0 =1	_____
15. Step length and height: walk a measured distance of 12ft twice (up and back). Four scores are required or 2 scores (a & b) for each leg. "Marked deviation" is defined as extreme substitute movements to permit clearing the floor. b. Foot clearance	a. Swing foot Does not advance a minimum of 12in Advances a minimum of 12in Foot does not completely clear floor without deviation Foot completely clears floor without marked deviation	= 0 = 1 = 0 = 1	_____ _____ Prosthesis Sound _____ _____ Prosthesis Sound
16. Step continuity.	Stopping or discontinuity between steps (stop & go gait) Steps appear continuous	= 0 = 1	_____
17. Turning: 180° turn when returning to chair.	Unable to turn, requires intervention to prevent falling Greater than 3 steps but completes task without intervention No more than 3 continuous steps with or without assistive aid	= 0 = 1 = 2	_____

18. Variable cadence: walk a distance of 12ft fast as safely as possible 4 times. (Speeds may vary from slow to fast and fast to slow, varying cadence.)	Unable to vary cadence in a controlled manner Asymmetrical increase in cadence controlled manner Symmetrical increase in speed in a controlled manner	= 0 = 1 = 2	_____
19. Stepping over obstacle: place a movable box of 4in in height in the walking path.	Cannot step over the box Catches foot, interrupts stride Steps over without interrupting stride	= 0 = 1 = 2	_____
20. Stairs (must have at least 2 steps): try to go up and down these stairs without holding on to the railing. Don't hesitate to permit pt to hold on to rail. Safety first, if examiner feels that any risk in involved omit and score as 0.	Ascending Unsteady, cannot do One step at a time, or must hold on to railing or device Steps over step, does not hold onto the railing or device Descending Unsteady, cannot do One step at a time, or must hold on to railing or device Steps over step, does not hold onto the railing or device	 = 0 = 1 = 2 = 0 = 1 = 2	 _____ _____
21. Assistive device selection: add points for the use of an assistive device if used for 2 or more items. If testing without prosthesis use of appropriate assistive device is mandatory.	Bed bound Wheelchair Walker Crutches (axillary or forearm) Cane (straight or quad) None	= 0 = 1 = 2 = 3 = 4 = 5	 _____
	Total Score _____/47		

Trial ❒ no prosthesis ❒ with prosthesis Observer _____ Date _____