Improvements for Lower Extremity Socket Design and Suspension for Children in the Developing World

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1. Abstract

Lower extremity prosthesis design and suspension has to manage the aspects comfort, control, balance and stability. According to survey publications among patients comfort turns out to be the most insufficient aspect. For sufficient comfortableness, a proper balance between biomechanical processes should be made, to obtain favourable pressure distribution, slippage, friction, shear and tissue responses. The developed world research tries to optimize the socket comfort, with techniques such as dynamic design, personal revisions and elastomeric liners. Prosthesis for children in developing countries are available, but these have to manage developing country problems, especially economic factors, however environmental factor should not be overlooked. Organizations and companies in developing countries are introducing custom-made. However, comparing to the western world, these sockets lack in comfortableness and suspension technology. Either recent publications about these technologies in developing countries are missing.

2. Register

3. Introduction

3.1. Lower extremity prosthesis and socket

In developed countries the main cause of lower extremity amputation is vascular disease. In the developing countries lower extremity amputations are mostly caused by trauma, related to land mines, industrial injuries or traffic accidents. Marks L. (2001). Land mines explosions cause about 26.000 new lower extremity amputations each year. Phillip R. (2001). Two surveys with demographic characteristics about children in a developing country with lower extremity prosthesis were found. In a survey in Tanzania, 85% of the child limb amputations were of the lower extremity. Loro A. (1999). In the other survey in Jordan this number was 53%. Fattah A. (2008). Lower extremity amputation can occur on different levels. These levels are partial foot amputation, ankle disarticulation, transtibial amputation, knee disarticulation, transfemoral amputation and hip disarticulation. Phillip R. (2001). The reported level prevalence for children in Tanzania was (in decreasing occurrence) trans-tibial, trans-fermoral, others. Loro A. (1999). In Jordan the same order was found. Fattah A. (2008).

A prosthetics limb consists of three basic components: the artificial foot, the extension and the socket. Cummings D. (1996). The knee joint is an extra, possible option.

The socket is the interface between the remaining limb and the rest of the prosthetic limb. and has direct contact with this stump. The socket determines the patients comfort to wear and the ability to control the prosthesis. Two aspects that determine these qualities are design, including fitting and alignment, and suspension. Strait E. (2006).

3.2. Goal of this paper

In this paper a literature study is performed to find the point of improvements children in developing countries face using a lower extremity prosthetic socket. It will form the basis for an upcoming design project which improves the design and suspension of the lower extremity socket for children in the developing world. At least 80% of the families of these children cannot afford western high-technology prosthesis. Cummings D. (1996). The project will carry out a simplistic and fitting solution for these patients, which will not be an expensive gadgetry, but still has good scientific approach. In this way the project tries to bring more and not less science to the developing world. With the project in mind this study tries to find an answer to the question '*What are points of improvement for design and suspension of the socket for children in developing countries?*'.

3.3. Study strategy

First the problems are defined following by the existing solutions, at least the short-comings of these solutions are found in the evaluation and the points of improvement are summed in the conclusion including a cause-effect and stakeholders diagram.

The problem definition with the research question *'What are the main problems in lower extremity socket design and suspension for children in the developing world?'* should be found in publications with the specific keywords '*prosthesis/prosthetic(s)*', '*lower extremity*', '*developed countries/world*', '*children*' and '*socket*', but are not available. For this reason a three-part problem definition is stated to cover all the problems. First the general problems in the design and suspension of the socket are defined, using publications with the keywords '*socket*', '*design*', ' *suspension*', '*lower leg/extremity*' and/or 'prosthesis/*prosthetic(s)'*. The most complete, recent ones were used. Second the problems in providing prosthesis in the developing world are defined, using publications found on www.patchproject.nl. At least the problems concerning lower extremity prosthesis for children in are defined, using publications on www.patchproject.nl.

The existing solutions *'What are the existing solutions in lower extremity socket design and suspension for children in the developing world?'* of socket design and suspension are divided by those of the western world and those of the developing world. Publications about the solutions in the western world are found using the keywords '*suspension*', '*design*', '*socket*' and/or '*lower extremity/leg/limb*'. The reviews were used. Publications about the solutions in the developing world are found on www.patchproject.nl.

4. Problems

4.1. Problem 1: Lower extremity socket design and suspension

The difficult aspects in lower extremity prosthesis are comfort, control, balance and stability. The higher the amputation level, the more magnified these aspects are. Hip prosthesis have the highest rate of rejection. Transfemoral prosthesis has more design and suspension challenges than transtibial prosthesis. Carroll K (2006). However comfort, control, balance and stability all form difficult aspects in design and suspension, these aspects do not all form a problem. Most patients reject their prosthesis temporary or permanent due to discomfort. Temporary loss of prosthetic use of the lower extremity amputee children occur at 52% due to discomfort, while only 23% due to prosthesis failure. Vannah W (1999). A socket must be comfortable, otherwise the patient lose control over the prosthesis, or even is not able to use the prosthesis.

The design and suspension has to be in a proper biomechical balance to provide a comfortable socket. Processes influencing this balance are pressure, shear, friction, slippage and tissue responses. Mak A. (2001).

4.1.1. Pressure

Pressure rises from the weight of the body of the patient and from contraction of muscles during active use of prosthesis. Pressures measured at the socket interface vary strongly among different sides, prosthesis, patients and clinical condition. Thus design and suspension of socket partly determine the pressure distribution. The pressure distribution is a critical consideration and should be proper to make it possible to use the prosthesis. Pressure leads to tissue distortion and pain. Mak A. (2001).

4.1.2. Slippage, friction and shear

Slippage is a consequence of a loose fitting, friction is an effect of slippage and shear forces rise from friction. All those three has to be in a proper balance to make it possible to use the prosthesis and are mainly determined by the design and suspension of the prosthesis.

The looseness of the fit could influence the coupling stiffness, increasing the slippage of the socket relative to the residual limb. More slippage increases friction and decreases stability. While less slippage decreases friction and increases stability, but increases pressures.

Friction is a phenomenon which occurs when forces acting between bodies in contact are opposite. Skin friction can depend on slip, materials and skin conditions. When friction existing, shear forces are acting on the skin surface. Shear forces leads to tissue distortion. Mak A. (2001). The smaller the friction, the smaller the shear forces, but the larger the pressures. Zhang M. (1996).

4.1.3. Tissue responses

Soft tissue of the residual limb at the edges and within the socket is subjected to a special environment. This environment is not naturally suited for the stump.

First, the skin undergoes abnormal biomechanical interactions: pressures and shear forces cause dynamic and respective loads, friction causes skin rubbing against the socket and excessive slip causes heath during the prosthetic use. Tissue responses to these external forces are complicated, involving pain, microvascular responses, lymphatic supply, metabolites, skin temperature and tissue deformation. Mak A. (2001). Temporary loss of prosthetic use due to tissue breakdown occurs at 16% of the lower extremity amputee children. Vannah W (1999). Second, the interface is a high-humidity environment, because the socket excludes air-circulation and causes sweat-accumulation. Mak A. (2001). Temporary loss of prosthetic use due to perspiration occurs at 12% of the lower extremity amputee children. Vannah W (1999). Third, the tissue may possibly react on the socket-material with skin irritations or allergic reactions.

These unfavourable environmental circumstances could break down the skin, even at skin surface as in deep tissues. However, prevalence and in

4.2. Problem 2: Providing prosthesis in developing countries

In the developed world the economics factors are favourable. People have life insurance, companies and other organisations provide innovative new-technology prosthesis and patients can work together with professionals to preserve or obtain an optimal functioning prosthesis. In developing countries these economic factors are mainly less favourable. Not only prosperity is a problem, environmental factors could be a disadvantage in providing prosthesis in developing countries.

4.2.1. Economic factors

The costs of lower extremity prosthesis vary among countries. In the developing countries the costs are approximately between $41 and $1.875 USD. Even when the costs can be cut as small as possible, still replacements and maintenance cost can't be avoided. Strait E. (2006). The health expenditure is according to the World Health Organization (WHO) in most developing countries less than $100 a year. World Health Organization (2008).

The prosthetic aid programmes in developing countries are generally of three types: i) research programmes organized by developed countries, ii) programmes that produce and/or maintain prosthesis in centres, iii) designed programmes that introduce the producing and/or maintaining of prosthesis where no centres are available. Cummings D. (1996). The centres are mainly localized in the villages or in a mobile clinic. However, the distribution, production and maintenance are insufficient comparing to developed countries. Not enough trained personnel is available, especially not who have the high level of skill to construct, fit, align and adjust a high-technology prosthesis. Cummings D. (1996).

4.2.2. Environmental factors

Environmental factors are: climatic, social and cultural factors and available material and forms of technology. These factors can form a barrier to provide prosthesis in developing countries.

Climatic factors can form a harsh environment for prosthesis. Especially a tropical climate shortens the lifespan of prosthesis. Wooden and resin prosthesis have only a lifespan of 18 months in a tropical climate.

Developing world social and cultural factors differ from the developed world. The social and cultural factors in the developing world differ widely among different countries. For example, people are more subjected to a more rural, farm-based or natural environment, people are sitting more frequently on the ground and people are tent to reach to self-assembly instead of a professional approach.

Available materials and forms of technology are different in each developing county and are even locally different.

4.3. Problem 3: Lower extremity sockets for children

The rate of success for lower prosthetic treatment seems to be higher for children. The time of use at 9+ hours a day for children is reported at 88% and for adults at 60-65%. The activity level for walking a day for children is reported at an average of 5.2 km and for adults at 0.7 to 1.3 km; for children five times the distance that reported for adults. Unless the higher time of use and activity level, the reported discomfort experience is much lower for children. Children have 16% moderate or worse pain versus 54-57% for adults. The respiration discomfort moderate to severe is 20% for children and 70% for adults. Vannah W (1999). An extra advantage form the skin of a child: the elasticity is coupled with excellent blood supply, providing better healing. Phillip R. (2001).

The fact that the rate of successive treatment for children is relatively high doesn't exclude that some aspects deserve special attention. The following aspect special for children can form a problem and deserve special considerations in lower extremity socket design and/or suspension: i) follow-up, ii) terminal overgrowth.

4.3.1. Follow-up

Children grow at ages between four and sixteen years at an average rate of 2 cm/year. During surgical amputation the growth plates in the bones need special attention and are preferable to stay intact to maintain simulations length at both lower extremities. Phillip R. (2001).

Frequent socket revision or replacement is preferable with children to accommodate their growth and stump development. Revision may be needed 3 to 4 times/year. A replacement may be required every 12-18 months. However, adults require replacement every 3-5 years. Phillip R. (2001).

4.3.2. Terminal overgrowth

The most common complication is caused by the skeletally immatureness of children: terminal overgrowth. Terminal overgrowth is excessive bone remodelling, leading to bone spurs. It does not occur after disarticulation amputation. It is most frequent below ages of 12 years and at the level of transtibial amputation first, transfemoral amputation second. Socket adaptions may delay surgical operations, but can’t avoid possible skin penetrations. Phillip R. (2001).

5.Solutions lower extremity socket design and suspension

Historically two types of sockets are used, patellar tendon bearing (PTB), offering areas of pressure and relief, and total surface bearing (TSB), offering distribution over the total contact surface. Reported for PTB sockets is the maximum pressure of 400 kPA, however the maximum pressure during walking was usually below 220 kPA. Maximal pressures among TSB sockets are lower. Nowadays mainly TSB socket solutions are used. In the western world different technologies are available to provide a socket limiting the biomechanical and tissue problems to increase comfort. In the developing world prosthesis are self-assembled out of locally available materials or produced, and mainly free provided, by organizations and companies.

5.1. Western world

The design and suspension of western world sockets is highly custom-made for each patient. The last years new systems are made and new flexible materials are available. These new technologies are used in new design and suspension approaches.

5.1.1. Traditional suspension

Although newer suspension techniques are usually preferable because they reduce friction and slippage, some individuals like to use an older suspension system, either for primary or secondary suspension. Examples of these traditional suspension systems are corsets, belts or sleeves. A cuff is tight packaged around the stump, with metal joints attached to the prosthesis. A belt can be rigid, for example leather, or elastic. The belt is attached to the socket and loops around the patient's waist. A sleeve is rolled on over the prosthesis and the stump. Carroll K (2006).

5.1.2. Suction suspension and pin suspension

A suction suspension system makes use of the vacuum effect and is a TSB socket. A pin suspension system makes us of a pin/shuttle system on the stump and in the socket and is a PTB socket. These techniques are two distinct additions to the traditional suspension systems.

A suction suspension socket is attached to the stump with vacuum between them. The vacuum-assisted suspension system (VASS) is the most important system. Is consists of a liner, suspension sleeve and air evacuation pump. The pump maintains a vacuum between the stump and the socket wall. The pump also can reduce perspiration. Carroll K (2006). The VASS claims to maintain a consistent fit. Vacuum in the space may draw fluids in the stumps during non-active-weight-bearing activities, forming the stump in the socket fitting. With this process the VASS promises less slippage.

The pin suspension system makes use of a pin/shuttle system. The pin attached to the stump, using a liner (Figure 2). A liner is a strong, flexible, thin sock, rolled on over the stump. It is strengthened over the palletar tendon and has a pin extending from the bottom. The pin snaps into a shuttle on the bottom of the socket and forms a lock.

Patients suggest a preference with a pin suspension system, based on taking approximately half as many steps and a shorter time needed to obtain an adequate fit comparing with a VASS . So the pin suspension system is suggested to offer more usability. Carroll K (2006).

5.1.3. Liners and sleeves

Like mentioned in section 4.1.2 liners are strong, flexible, thin socks, rolled on over the stump. Liners add a cushioning layer between the socket and the stump. They help to spread the transfer of load. Emrich R. (1998). They also could contribute to suspension, because they introduce suction and tackiness between the interface space. The first liner where made of foam and these are still used. However, more modern liners are developed to offer better suspension, durability and/or cushioning. The modern liners are gel liners made from silicone gel or other elastomers. Klute K. (2011).

Liners could have different material properties, which can be used for different loading conditions. It is suggested that stiff liners are the best for patients with a lot of soft tissue and soft liners are the best for bony stumps. Sanders JE (2004). The thinner the liner, the higher the patients sense of control. Also a study suggests that liners could take sweat and heat away and decrease perspiration. However researchers have proved that liners help to distribute pressure and reduce pain, evidence of different liner materials for specific clinical situations is not well understood. Klute K. (2011).

As mentioned in section 4.1.2 sleeves are rolled on over the prosthesis and the stump. They provide primary or secondary suspension. Sleeves are meant to be airtight and sealed on top of the socket, to prevent air from going into the interface space, to obtain fitted suspension. They are made of synthetic vulnerable material and should be replaced regularly. Carroll K (2006).

These closed states of the liners and sleeves can cause perspiration problems, especially for patients in hot or humid environments. Carroll K (2006

The latest technology is to incorporate grooves and pumps to facilitate dehydration. Also valves can be used to release air during use and optimize suction and fitting. Carroll K (2006).

5.1.4. Dynamic sockets

For an ideal comfortable situation, sockets should be changing and dynamic during use. For this reason dynamic sockets are developed. Dynamic sockets are specific for a patient's anatomy and are designed to allow the contraction and relaxation of muscles. This promotes and vital and strong stump and is mainly an advantage for transfemoral amputations.

The dynamic sockets are more comfortable during walking and sitting. For walking, the dynamic sockets are combined of thin, elastic materials for the inner frame and composite materials for the outer, supportive frame (Figure 1). This design makes the socket expand when the muscles fires and clamps onto the stump during muscle relaxation at the swing phase. For sitting, the posterior wall of the inner frame is flexible and in the outer frame cut-outs are made. This makes the socket expandable for stump weight during sitting. Carroll K (2006).

An dynamic socket is a result of an optimization process facilitated by the patient and the prosthetist. Many small and large modifications are made on especially the outer frame. Using test sockets and computer scanning techniques, this fitting process is improved.

5.1.6. Donning techniques

Donning of prosthesis is putting on of prosthesis. Proper donning is important to maintain socket suspension. Donning can take a lot of the patients energy and can be painful for the skin. Two main techniques to promote more gentile and energy-efficient donning are available. The first is a sock. After putting the sock over the stump, it must be pulled gently out of the socket through a valve. In this way the stump slips into the socket. The sock can be made of cotton, can be an Ace bandage or can be a nylon slip sock made of parachute material. Another approach to facilitate donning is the wet approach. The socket has to be made wet with a lotion, in this way friction is reduced.

Figure 1. Dynamic socket
Ottobock.com

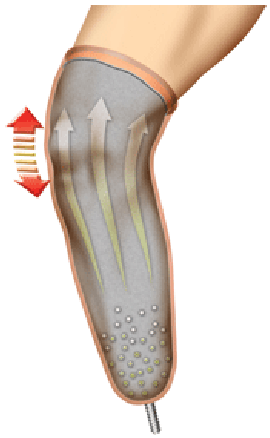

Figure 2. Gel liner with pin suspension
Amputeesupplies.com

5.2. Developing world

Existing sockets in the developing world makes use of either designs and suspensions developed by local people or the design and suspension developed by local organizations possibly cooperated with the western world. Local solutions are plastic/wooden platforms, bamboo/PVC wires, wooden/leather construction sockets, old tires sockets and sockets made out of bicycle and plaster bandage. Organizations have developed more technical sockets with thermoplastics using a positive mold or CAD/CAM technique.

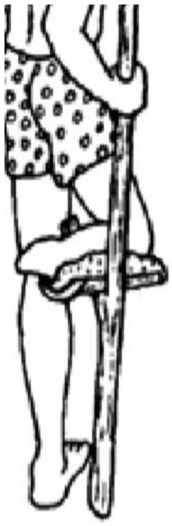

*Figure 3**

*Figure 4**

*Figure 5**

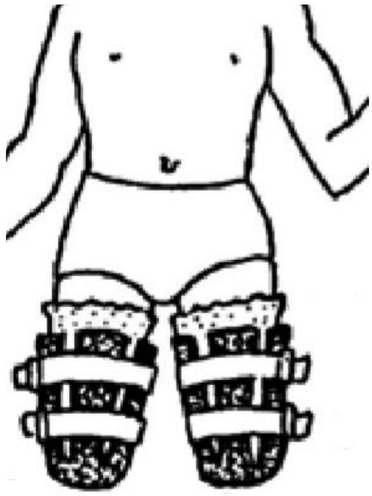

*Figure 6**

**Strait E. (2006).*

5.2.1. Plastic or wooden platforms

Pole and crutch limbs are the most simple lower extremity prosthesis. The prosthesis is a pole of plastic or wood and can be secured to the stump with a hand-held pole or with bands and straps.

The socket is a curved platform of plastic of wood with a pad (Figure 3). Either a leather strip can be used or a hang-up system. Strait E. (2006). This socket can lead quickly to long term fitting problems and decrease of muscle substantial due to wrong alignment.

5.2.2. Bamboo, PVC wires

The bamboo/plaster leg and the pvc/plaster artificial leg are bamboo or plastic pipes attached to a foot.

The socket is a combination of socks with plaster bandages around the stump, fold out of many bamboo or pvc wires and a rubber section in between (Figure 4). Strait E. (2006). This socket can lead to long term fitting problems, but have better alignment than section 5.2.1..

5.2.3. Wooden or leather construction sockets

Wooden/metal/leather custom-made constructions are popular, but are time-consuming and require technic skill to produce, although the required techniques are traditional methods.

The sockets are curved from a block of wood or made from wet leather stretched over a positive model (Figure 5). Strait E. (2006). Leather construction is more comfortable than wood or one leather strap, because it is self-relieving and correcting.

5.2.4. Old tires

Patients with bilateral amputations in developing countries use often residual limb protectors. They promote protection for de stump and promote a lower centre of gravity to increase balance and stability, but have no artificial joints, leg or feet. Meaning that the this prosthesis is just a socket without other parts. These residual limb protectors are mostly made out of old tires.

The socket is an x-shaped tire piece attached to the stump with straps with a protective sock in between (Figure 6). Strait E. (2006). The socket restrict severe in range of motion, but are time and cost efficient to produce.

5.2.5. Plaster bandage with foam with support of bicycle parts

An adjustable bicycle limb is a prosthesis made out of bicycle parts. The components of the artificial leg are adjustable for children and the foot is made from the seat.

The socket support is made from bended back wheel support and a wooden disc. The socket is made directly over the stump from plaster bandages and covered with foam inside. The support and the socket are attached with plaster bandage around the arms of the support. The suspension is performed with a belt around the waist. Strait E. (2006). This socket cost efficient and has increased comfort provided by the custom-made fitting. However, the suspension will cause slippage and cause tissue irritation/breakdown.

5.2.6. Thermoplastic indirectly shaped sockets using a positive mold

Examples of prosthesis provided by organizations are the Multi Limb, the Sathi Limb or the upcoming International Committee of the Red Cross (ICRC) prosthesis. The prosthesis are light weighted, custom-made in 5 hours and provided free at costs by the organization.

The socket is made out of thermoplastics like high-density polyethylene (HDPE) or polypropylene (PP). There materials are lightweight, water-resistant, non-corrosive material, can be adjusted after heating and can be available in skin-colour. This material heated and formed over a positive mold to form the socket fit. Leather strips are used for suspension. Strait E. (2006). Andrysek J (2010).

5.2.7. Thermoplastic indirectly shaped sockets using CAD/CAM

The CAD (computer-aided design)/CAM (computer-aided manufacture) Monolimb is a new, well-functioning, modern technique in the developing countries. The reason for the success is that CAD/CAM Monolimb production needs a low level of skill and takes less than four hours. The costs for these prosthesis are $35, excluding the computer technique costs.

The socket is directly manufactured out of a thermoplastic sheet using computer output. Strait E. (2006).

5.2.8 Directly shaped socket

Another potential approach is to form the socket directly over the stump eliminating the casting and positive mold steps. This could be a time efficient technique. Nevertheless the technique is not used in the developing countries neither the western countries. Cha. et al report a technical description of a potential material for directly shaped sockets. Andrysek J (2010).

6. Evaluation: Short-comings in lower extremity socket design and suspension for children in developing countries

Sockets for children must allow small modifications in design to accommodate growth and development. Preferably the design and suspension can be modified over a long time of growth and development to delay replacement.

The difficult parts of a socket are offering comfort, control, balance and stability. These aspects must be reached in the design, including fitting and alignment, and suspension. Although it turns out from surveys among lower extremity, western world prosthesis users that the function aspects control, balance and stability are mostly easy managed in the prosthesis, but the comfortableness is the difficult, failing part.

To solve this main problem about comfortableness sockets must distribute power in the most comfortable way and certainly must not cross the thresholds of pain. A proper choice of slippage and thus friction is needed to balance the requirements of effective prosthetic control and minimization of interface comfortableness. Unfavourable environmental skin circumstances at the socket interface could lead to skin breakdown. These biomechanical processes influence the interfacial hazards. Nevertheless, it is not possible to have them all in optimal condition: a proper choice in design and suspension should be made to preserve the best balance.

The solutions in the western world researchers and companies are developing innovative, more comfortable sockets. Suspension systems aided with sleeves with valves and thin, elastomeric liners are made to optimize comfortableness. The most comfortable design can be reached with a dynamic socket, requiring much personal modifications.

Besides, next to the design and suspension challenges, in the developing countries the problems to provide prosthesis are appended with more issues. Low health expenditure, the lack of less crystalized organisations and trained personnel and other environmental factors form a barrier to provide prosthesis in developing countries. No studies were found with characteristics about the children in developed countries provided with prosthesis.

The existing solutions in the developed counties socket design and suspension are traditionally made of locally available materials and techniques. The past years more medical technology approaches are brought to these countries by organizations and/or the western world: sockets made out of thermoplastics with optionally using computers. These sockets have a custom-made fitting. Apparently for children in developing countries prosthesis are available. Publications with demographics about the providing of prosthesis are not available, but based on the barriers for developing countries, the prosthesis providing is insufficient.

Comparatively, in the developed world prosthesis socket technology seems to control the control, balance and stability aspects, the difficult point is mostly the comfort. In the developing world socket technology runs behind time and is just on the point of custom-made fitting. No surveys were found reporting the comfort of sockets in developing world, neither studies about the functioning of suspension in the developing countries, nor studies reporting the possibility for children to make the small modifications needed in their socket fitting in developing countries. Although socket comfortableness technology remains a challenge in the developed countries, this technology still has to start in the developing countries. The need for this technology must first be examined in surveys among (children) patients in the developing countries and afterwards this aspect must be added to socket design and suspension.

7. Conclusion: Points of improvement for design and suspension of the socket for children in developing countries

Socket for children in developing countries are partly available and mostly offer control, balance and stability. The problems of sockets for children in developed countries are summarized in the cause effect diagram (Diagram 1). These problems can be converted to points of improvement. Points of improvement for design and suspension of the socket for children in developing countries are:

- Low costs and/or locally manufactured, to survive economic and environmental factors.
- Durable, to be attractive for the developed world.
- Adjustable for small fitting modifications, to grow along with children.
- Proper biomechanical balance, to offer comfortableness.

If these point could be include in the sockets for children in developing countries, these sockets should be more widely available and should be, as wished in the introduction 'will not be an expensive gadgetry but still has good scientific approach' looking at control, balance, stability and also sufficient comfort.

These points must be considered during the design phase, the import of prosthesis from developed countries or the introduction of a new prosthesis production process in the developing countries.

The stakeholders dealing with sockets for children in developing countries from design until use phase, are summarized a stakeholders diagram.

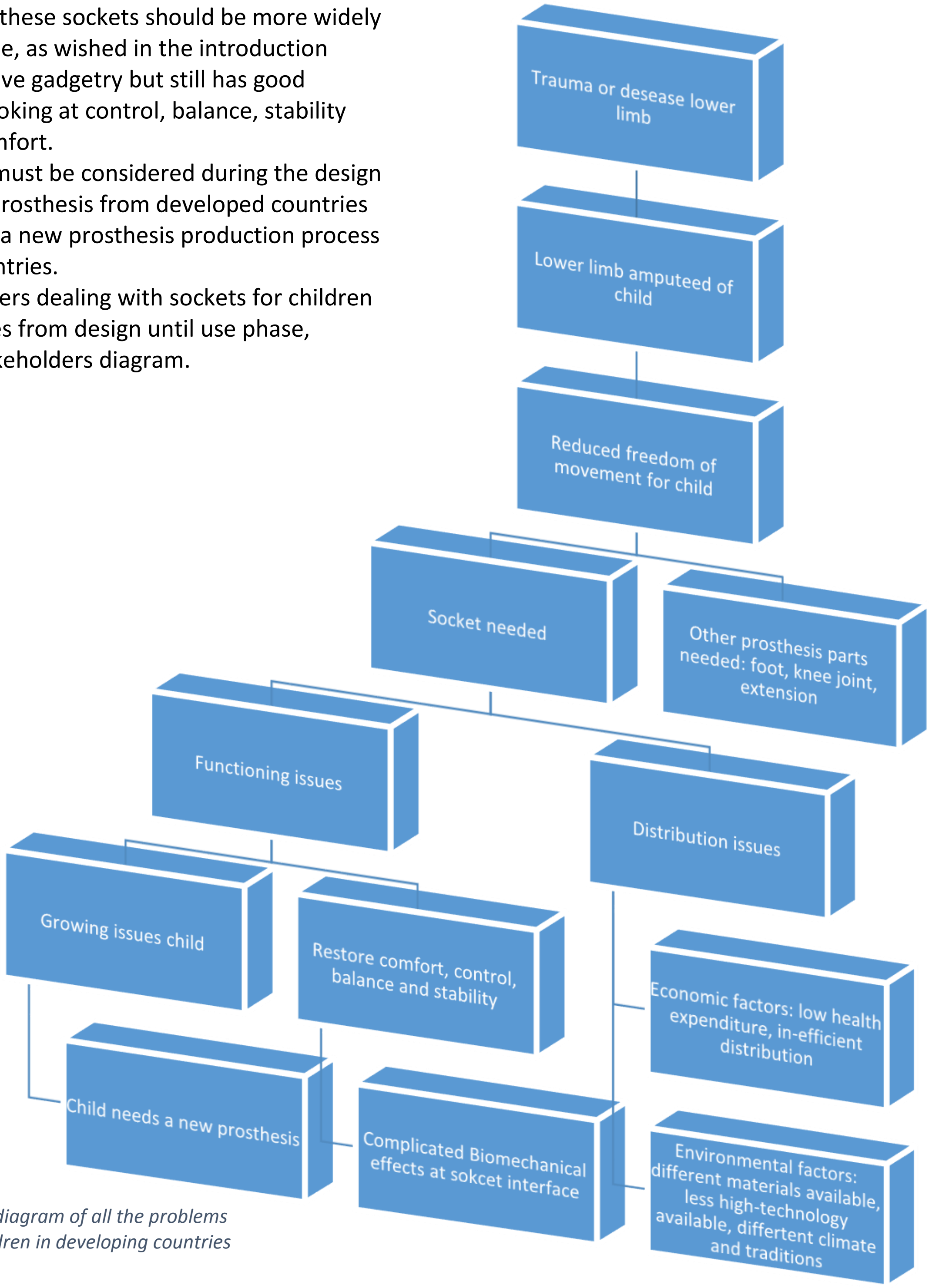

Diagram 1: A cause-effect diagram of all the problems concerning sockets for children in developing countries

Stakeholder	Characteristics	Expectations	Potentials and deficiencies	Implications and conclusions
Child in developing country	Missing lower limb, reduced freedom of movement, social and emotional problems	Increase in freedom of movement, a proper working, comfortable prosthesis	Uses the prosthesis a lot of time	Child need properly working, comfortable and safe prosthesis, although there is no money available
Family child	Reduced freedom of movement for child, have a low expenditure	Increase freedom of movement for child, spend the smallest amount of money as possible	Is tent to buy food instead of prosthesis	Child need properly working, comfortable and safe prosthesis, although there is no money available
Designer western country	Designs a part of the lower extremity prosthesis in de western world for children in developing countries	Increase freedom of movement for child, design a proper working, comfortable, ect., answer the expectations of all the stakeholders	Wants to have success at all areas	Main goal: create properly working and cheap prosthesis
Other designers western countries	Designs (a part of)the lower extremity prosthesis in de western world or for the western world	Increase freedom of movement for patients, design a proper working, comfortable, ect., answer the expectations of all the stakeholders	Designers can forget or miss each other's work, prosthesis products can have patents	The designer have to together with other designers, the patent issues should not be forgotten
Charity organization	Stimulated good circumstances for people in developing countries	Increase freedom of movement for child, solve social and emotional problems child, help families, save and properly working prosthesis	Can spend money for design and/or distribution	For all other stakeholders it is best to have as much charity support as possible
Manufacturer	Produces the prosthesis in the western world or the developing world	Produce proper working prosthesis, guarantee production safety issues, earn money	Can be in the western world or in the developing wold	Prosthesis should be made out of an easy processable, low-cost, adjustable, material
Transport company	Brings the prosthesis to a place in the developing world were the child lives	Efficient package, clear destination, safe destination, earn money	Needed in the western world and/or in the developing wold	Prosthesis must be designed to pack small, the reduce costs
Provider developing county	Provides the prosthesis for the child	Simple, safe and properly working prosthesis, low costs, good distribution	Can be already existing programme or must be new-settled	It is most favourable to have a well-crystallized, professional programme, with the lowest costs as possible
Prosthetist organization developing country	Helps the child with revalidation and possible modifications for the prosthesis	Strong, safe and properly working prosthesis, small modifications easily possible, low costs	Organization can be of different levels: local, professional, non-professional, governmental, western country settled	It is most favourable to have a well-crystallized, professional organization, with the lowest costs as possible, with facility to adjust prosthesis

Table 1: Stakeholders analysis for a lower extremity prosthesis socket for children in developing countries

8. Acknowledgement

This study is a part of the Patch Project founded by Bram Sterke at the Rijksuniversiteit Groningen. The goal of the project is to create an open-source platform on which people all over the world can obtain information about prosthetics for children in developing countries, launched on *www.patchproject.nl* and *www.patchproject.net*.

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