Designing Functional Beauty through Additive Manufacturing: Prototyping of Running-Specific Prostheses Using Selective Laser Sintering

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Abstract

The objective of this research is to establish a new methodology of designing aesthetically and functionally satisfying mass-customized products that fit individual bodies. The primal phase of this study, the prototyping of additive manufactured Running-Specific Prostheses (RSPs), is shown in this paper. The focus of this work is to present the capability of manufacturing such products by using Additive Manufacturing (AM), especially Laser Sintering (LS). The first section describes the method in which a design process that uses AM technologies is established, aiming mainly to achieve a functional product that is also aesthetically pleasing. The latter section presents engineering verifications of previously designed prostheses, and the application of structural improvements to achieve enough reliability for user tests. The improved prosthesis was tested by a transtibial amputee runner; user review and remaining issues are reported.

Introduction

AM technology has received great attention in recent years, however, its actual usage in the industry is limited. It is usually used as a fundamental prototype for mass products (generally referred to as Rapid Prototyping) and to produce various types of jigs for large-scale factories (Rapid Tooling). These types of applications can be beneficial due to the speed and simplicity of the AM process. Recently, there are more final products being manufactured with AM, such as aviation parts [1] and in the medical industry [2]. However, it is estimated that 90% of the products manufactured by AM are mainly prototypes, while less than 10% are final products [3].

For that reason, it can be pointed out that the AM process is inferior in accuracy, speed and cost when comparing to existing manufacturing processes such as subtractive manufacturing and injection manufacturing. According to Niino [4], if the performance of each process is taken into consideration, AM has more weak points than existing manufacturing processes. To accelerate the popularization of AM technology, a technical improvement that resolves these negative aspects is desirable. On the other hand, showing new value-added products that make use of the AM technology benefits is crucial.

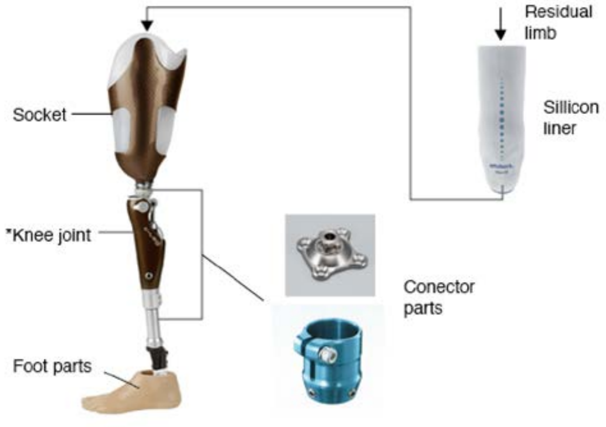
As previously described, AM process' speed and simplicity are clear advantages. On the other hand, its flexibility of manufacturing freeform designs with almost no limitation is more notable. The AM process enables making objects that existing processes cannot manufacture, such as highly complex freeform designs, minutely detailed objects and multi-layered inner structures. Niino [4] calls this characteristic a Complexity, and points out that, in the future, the likelihood of the AM market expanding depends on finding the applications that could maximize the benefits of Complexity rather than its speed.

Additionally, AM technology is more suitable for mass-customized production contrasting to existing production technologies. The hearing aid industry has already started to utilize AM and more than 15 million hearing aid units have been made [5]. There is also a movement of manufacturing customized shoe soles: some companies have created supplying soles that are optimized for individual foot shape by using AM technology [6].

Making practical use of these benefits, we aim to establish in this research a methodology of designing value-added products that fit individual bodies. This project is considered a first milestone for a bigger goal, as we wish to create RSPs by using plastic-based LS technology. Designing and manufacturing prostheses is mainly for a minority of people. Therefore, existing manufacturing systems that presuppose mass production cannot fit its individual needs sufficiently. This circumstance can be the cause of the problems that are described in the following chapter. As we stated previously, the AM process will sufficiently adapt for less volume and individually customized production. Therefore, an AM based system could generate new value while solving existing problems. Although specific information about structure of prosthetic legs will be given in the next chapter, in this study we mainly focus about the development of prosthetic sockets.

The present situation of prosthetic legs

The structure of prosthetic legs that are generally used is shown in fig. 1. They can be roughly divided in three sections: the first is called the socket to which the amputee's residual limb is attached, the second is the foot part that provides contact to the ground and the third is another connective part and the joints between them. In terms of RSPs, leaf springs take the place of the foot parts and are usually made of CFRP (fig. 2).



*Knee joint does not be included in the case of below-knee prosthesis.

fig. 1 The structure of prosthetic legs

fig. 2 RSP structure

As mentioned above, prosthetic legs are based on a standardized module-assembly system. Although that allows the supplying of affordable prostheses by combining metal parts, their appearances end up coming out quite unrefined. Therefore, amputees normally hide their prostheses under their clothes, a fact that has prevented normalization for the user. Meanwhile, sockets are completely custom-made products that depend on the prosthetist's craftsmanship. Fully handmade processes are still very common nowadays - almost no digital manufacturing tools are used. This could end up providing products that have an unstable design quality in contrast with other industrial products. Additionally, the manufacturing time and costs would be increased and would eventually slow down the spread of prosthetic legs in regions that do not support financial aids.

The significance of applying AM for prosthetic legs

AM technology can automatically manufacture complex freeform objects like sockets by using 3D data. Hence, if prosthetists could use CAD software, they would be able to exclusively separate their designing operation from traditional manufacturing process and they could concentrate on improving its quality or use their extra time for designing another socket. Accordingly, while decreasing the total cost of making sockets, prosthetists could respond to a greater amount and a wider range of user demands. The quality of the products would be mechanically stable at the same time.

On the other hand, AM enables to partly integrate the socket, the connective parts and joints into one part. While being fit for the amputee's individual set up, designing these integrated sockets that are both functionally and aesthetically pleasant is technically possible. Moreover, by using the freeform characteristics of AM, there is a possibility of realizing a superior performance in strength and lightweight properties.

Notably, we decided RSPs are an obvious example indicating possibilities that are mentioned above. Comparing to regular prosthetic legs for daily use, RSPs need more strict strength reliability and must be more lightweight. Additionally, as sport equipment, a well-designed appearance could give a mentally positive influence for audiences and athletes themselves. Beyond the traditional values of prostheses - such as reproducing missing body parts – we also suggest that it will be significant for both amputees and society to create beautiful and high-performance prostheses that can be exposed, rather than hidden.

fig. 3 Sprinting with a RSP

Objectives

As an early phase of this study, the process of primal prototyping of transtibial running-specific prostheses is shown in this paper. One transtibial amputee athlete participated in this study. First, an Additive Manufactured RSP (AMed RSP) was developed for that athlete. After collecting sufficient knowledge, we will attempt to apply this to other athletes. The profile of the athlete is stated in table. 1 below. The athlete is capable of sprinting 100m in less than 14seconds. During sprinting, the maximum load that strains the prosthetic socket is higher than normal; therefore, we decided this case is reasonable for a primal trial.

table. 1 The profile of the athlete

Age	22
Gender	Female
Prosthesis	Left foot transtibial prosthetic leg
Competition	Took part in Paralympic, IPC Athletics World Championships and others

The existing RSP that is used by the athlete is composed by a CFRP-made socket, a carbon leaf spring Cheetah Xtreme category5 (Össur hf.), and titanium made internal pyramid connecting adaptors. The appearance of the RSP is shown in fig. 4 underneath.

fig. 4 The existing RSP that is used by the athlete

In this study, 3D digitizer and CT scan were used to measure the form of whole RSP that is referred above. The inner surface form of the prosthetic socket that is attached to the residual limb was extracted exclusively, and was used as a basis of design. Although we consider it a final goal to scan the human body directly by using digital equipment (such as a hand-held 3D scanner), we used a different process because this is our first attempt.

Establishing design concept

Before establishing the design concept, the problems behind the design of existing RSPs were taken into consideration. It is clear that, although existing RSPs functionally enable amputees to run, the aesthetic appearance and the regard for user-centered design are inadequate. The shape of the prosthetic sockets is quite similar to the shape of the amputee's residual limb, so it can give the user a somewhat painful reminder. Additionally, the mechanical parts that are connected to the socket do not help create a visual harmony between the RSP and the human body. Furthermore, the sharp edges of those components can sometimes injure the other foot. Considering these situations, it can be said that an industrial designer taking part in the manufacturing process and improving aesthetic value and usability can be very beneficial.

On the other hand, both the functionality that the RSP should achieve and the manufacturing characteristics of plastic-based AM processes were taken into consideration. Each item is categorized and listed as follows:

Functionalities that the RSP should achieve:
- Structural strength that can withstand human maximum speed running.
- Being lightweight while also having enough strength, as described above.
- Connectable structure for existing standardized parts such as leaf springs.

Manufacturing characteristics of plastic-based AM processes:
- At this point, the material is Nylon12.
- Almost no limitation in manufacturing a highly complex freeform design.
- A form that allows extra material powder to be completely removed is preferable.

Taking the above list into consideration, we attempted to generate a design concept. As a first step, numerous pictures were collected of existing products that were made by AM processes, of sports equipment, organic structures and so on. Among them, the structure of bones was especially striking since the behavior and functionality of the bone structure seemed reasonably suitable for the AM process.

The bone structure is composed of bone tissue, cartilage, periosteum and bone marrow. The bone tissue forms most of the rigid part of the bones and is comprised of the cortical and cancellous bone. The cortical bone is the outer shell of the bone structure and consists of a high density of cells, being therefore harder and stiffer. The cancellous bone (fig. 5), also known as trabecular or spongy bone, is the inner side of the bone. It is made of porous tissue and has a honeycomb-like network structure of plates and rods. Due to these characteristic structures, the bone is both relatively strong and sufficiently light. The bones of birds (fig. 6) are especially strong and lightweight in order to be suitable for flying, and their structure consists of numerous trussed trabeculas in a hollow inner space.

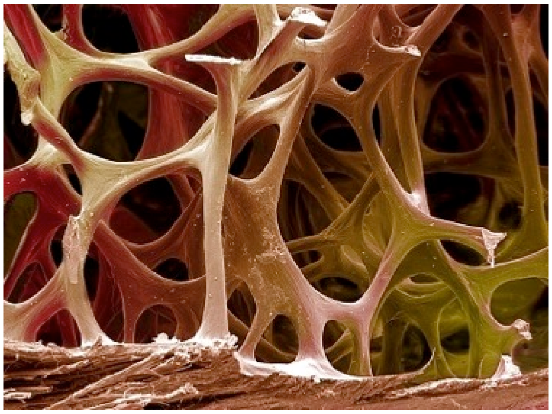


fig. 5 The cancellous bone

（http://m.inmagine.com/image-spl007312-Bone-tissue%20-SEM.html）

fig. 6 The cross section of a bone of birds

（http://www3.famille.ne.jp/~ochi/kaisetsu-01/kouzou.jpg）

These characteristic structures are generated as a result of the bone remodeling process done by osteoclasts and osteoblasts. By responding to mechanical stress, the structure is remodeled to increase strength around regions where it has been highly stressed and, in the opposite case, decrease density in areas with less stress. This physiological effect is generally known as a Wolff's law.

Bone remodeling, as we stated above, can be seen as a kind of structural optimization and it fits AM technology. By putting material in an appropriate amount and form around where it's needed, the bone can achieve effective strength and become more lightweight. In addition, AM technology is capable of manufacturing complex structures with almost no limitation, being therefore able to also include highly intricate structures inside. In the end, we decided to use bone structures as a main design concept reference.

As a result of the above researches, we named the new design concept "the trabecular structure concept". It can be described as follows: a large number of small beams extend from around the residual limb to the leaf spring connecting section. The beams compose a complex structure as they cross and combine. The density of the structure increases where stress is applied while it decreases in other parts in order to remain lightweight. The outer form of the trabecular structure follows the smooth curved surface in order to match the appearance of the socket with the human body shape. Additionally, the holes and cavities of the structure will help extract the surplus material powder from the inside.

Based on the design concept above, Yamanaka made specific design sketches. As seen in fig. 7, the appearance of the socket was defined by numerous sketches.

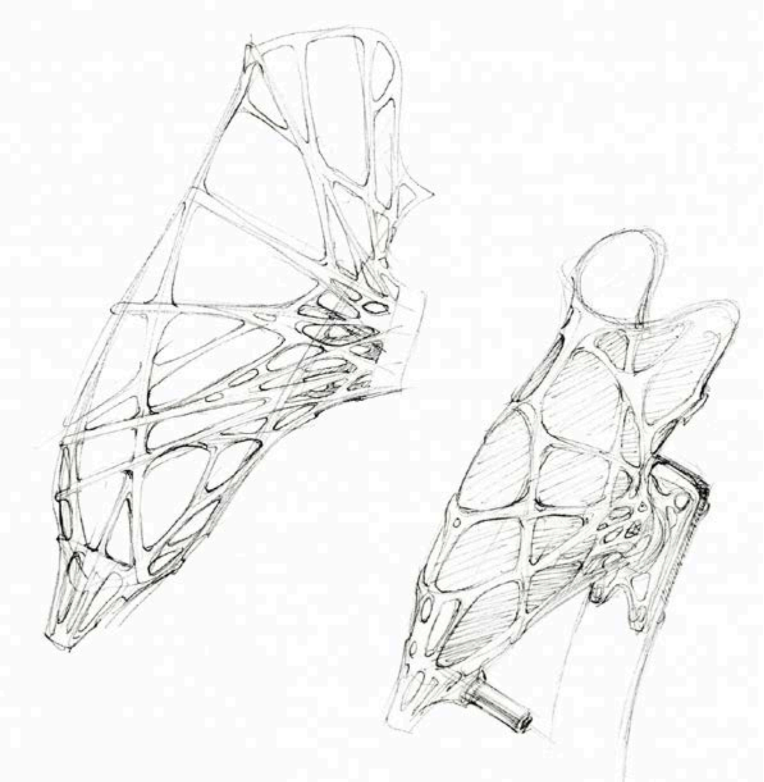


fig. 7 the specific design sketch

Manufacturing the design concept model

A study model that presents the design concept was made on the early research phase. The purpose of the model is to share the exact image of the design concept and to enable the discussion of improvements on the later phase of the research with the research members.

Firstly, by making reference to the design sketch, the 3D model of the socket was made. The CAD software that we used was Rhinoceros 5 for MAC (Robert McNeel & Associates). Secondly, the model was manufactured by an LS type AM machine RaFaEL300 (Aspect inc.). The maximum work size of the machine is 300mm in both width and length and 370mm in height. The work size allows the socket to be manufactured without parting it. The material powder ASPEX-PA2 (Aspect inc.), which is mainly composed with Nylon 12, was used to manufacture the socket.

The manufactured socket is shown in fig. 8. In the several early attempts, the socket was not able to attach to the residual limb because of form inaccuracy. After adjustments to the machine were done, we succeeded in manufacturing a socket that has sufficient accuracy. Afterward, a test fitting was done as seen in fig. 9. As we stated previously, although the socket doesn't include fully complete functionality on this phase, it was possible to attach, stand up, and walk.

fig. 8 The design concept model

(Photo by Yasushi Kato)

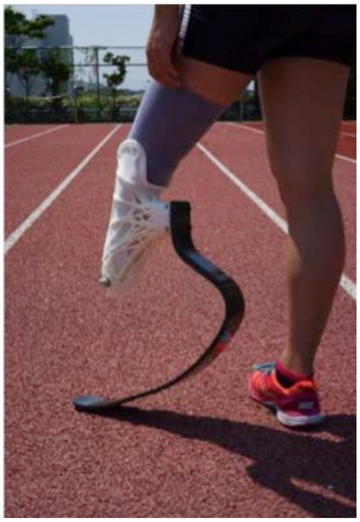


fig. 9 Test fitting

On this phase, we additionally carried out the research outreach activities mainly to research about impressions of new design concept. We organized an exhibition “Designing Body Making Beautiful Prosthetics” during June 4th to 14th 2015, in a gallery of The University of Tokyo. The design concept model and the research promotion movie were exhibited to public as seen in fig. 10. We interviewed visitors for their impressions and received advice from external technical experts, which were of benefit to the research.

fig. 10 Exhibition (Photo by Yasushi Kato)

Determining the strength benchmark

As a next step, we applied improvements to the socket so that it could achieve an adequate reliability for the running tests. The strength benchmark was estimated first. According to the benchmark, several components of the socket were developed.

Firstly, we asked the athlete to do a maximum speed sprinting while using an existing RSP so that we could take a slow motion movie of it. As a result of image analysis (fig. 11), it was estimated that the carbon leaf spring was deformed downward approximately 96mm.

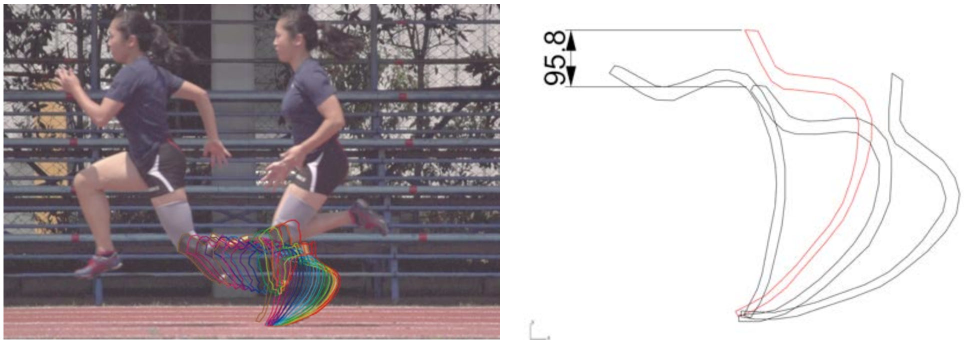


fig. 11 Image analyses

Secondly, we measured the spring constant of the leaf spring so that we could be able to estimate the elastic force of it. A carbon leaf spring Cheetah Xtreme category5 (Össur hf.) was used for the compression experiment (fig. 12).

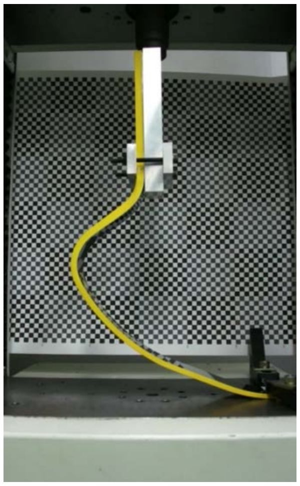


fig. 12

The compression experiment

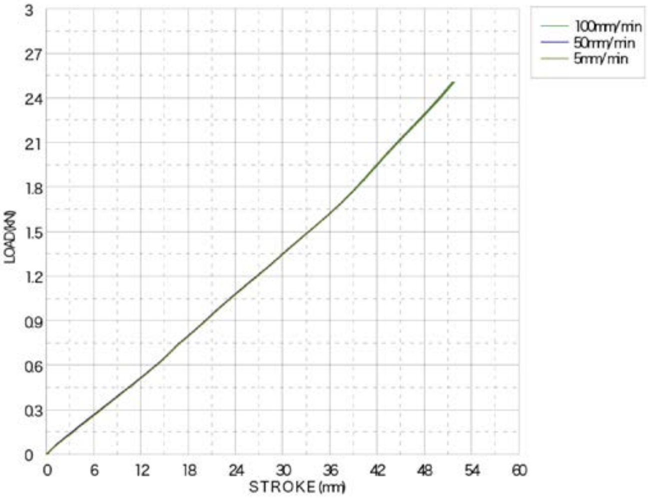


fig. 13 Load vs stroke trace,

X-axis refers stroke, Y-axis refers load

The conclusion was that the spring was deformed downward 52mm as it was stressed with 2.5kN load (fig. 13). Hence, the spring constant was,

$$k=P/\delta=4.81\times10*4[N/m]$$

As a result, it can be estimated that approximately 4.6kN of elastic force was received the leaf spring while sprinting. Due to the law of action-reaction, the prosthetic socket received the same amount of load.

According to the estimation, the strength benchmark was determined; the socket should resist 15kN (FOS of 3) of vertically downward structural load on the central axis of the socket.

Structural improvement

While we designed the design concept model, the outer trabecular structures and the inner structure of the socket were designed as we prioritized aesthetic quality rather than the functionality. As a next step, structural improvement is needed to surpass the strength benchmark. Modifications of the CAD data of the socket were repeated, making reference to Finite Element

Method (FEM) analysis.

Through the improvement, it appeared that the modifications of the inner structure highly affected the total strength of the socket. AM process is superior in manufacturing highly complicated freeform objects; hence the modifications previously mentioned match the characteristics of AM technology. The two pieces of topology optimization software such as Optishape-TS (Quint Inc.) and solidThinking Inspire (Altair Engineering, Inc.) were utilized to generate referential form models that would be effective for increasing structural strength.

A cross section of the socket in its primal phase is shown in fig. 14. Modifications are applied afterward mainly to increase the complexity of the inner structure (fig. 15-16). The shape of the outer trabecular structure was simultaneously redesigned. The corrected models were produced at a high frequency by utilizing an AM machine as a Rapid Prototyping tool

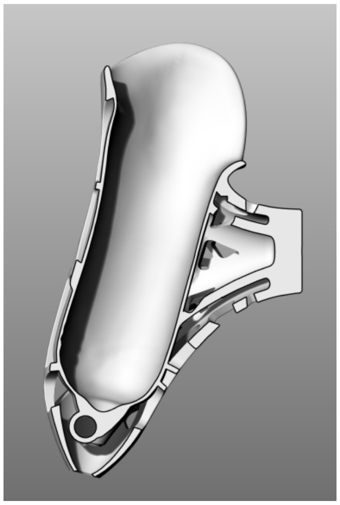


fig. 14
Primal phase structure

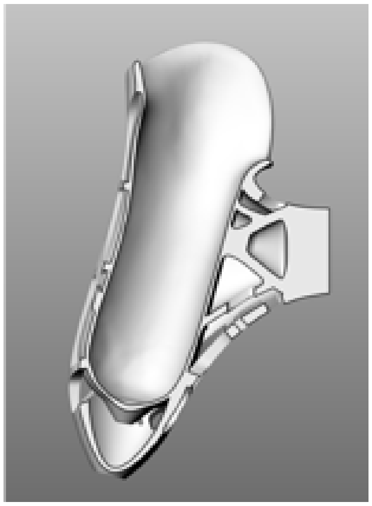


fig. 15
Mid phase structure

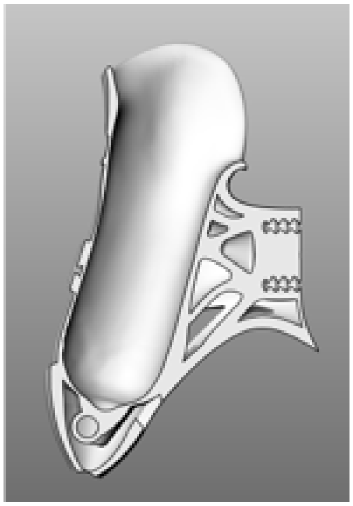


fig. 16
Current structure

Designing the internal adaptor

For practical use, a firm connection between the socket and the leaf spring is crucial. On the design concept model phase, the leaf spring was attached to the socket with standardized M6 bolts and nuts. There was a concern that the stress concentration would occur around the cavities that enable the nuts to be set in the socket. As a result of a compression strength experiment, it was noted that the connecting section of the socket that includes the cavities was broken by approximately 5kN of structural stress (fig. 17).

fig. 17 Cracked cavities

Accordingly, an alternative solution was needed. The solution should assume the following:

1. Maintain a firm connection between the socket and the leaf spring while sprinting.
2. Transmit the structural load over a large area to reduce the stress concentration on a Nylon part.
3. Preferably integrate the adapters into the socket without post-processing.
4. Be based on the characteristics and the limitations of AM process.

As a result of the design work, we designed the method that uses existing bolts and internal adaptors that are made with metal. The internal adaptors are inserted into the back of the socket and the leaf spring is attached to those adaptors by using standardized bolts (fig. 18).

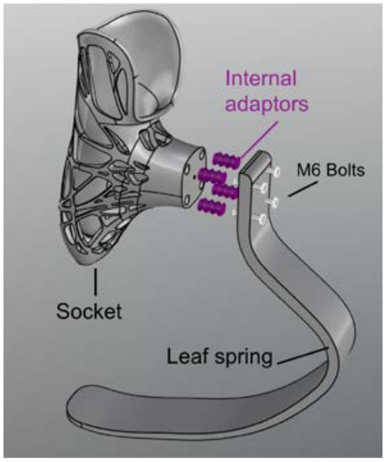


fig. 18 The Structure of RSP in case of using the internal adaptors

The adaptors were manufactured by a subtractive process. 5052 aluminum alloy was used to manufacture the adaptors (fig. 19). The length of the adaptor is 25mm and the maximum diameter is 14mm. There are male screw threads that are characterized by the specific screw profile on the outer periphery of the adaptor. The screw profile (fig. 20) is composed of arcs and tangents to avoid stress concentration. On the central axis of the adaptor, there is a hole with internal threads corresponding to a standardized M6 bolt.

fig. 19

The internal adaptor

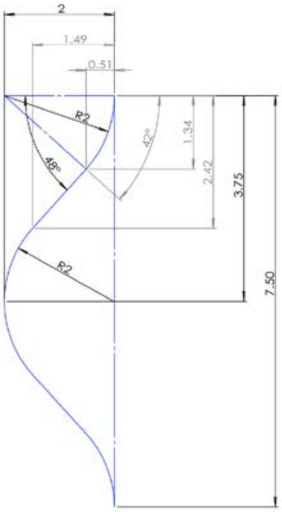


fig. 20

The internal adaptor

Designing the running test model

By integrating the knowledge obtained previously, the socket was redesigned as fig. 21 shows and the sketch was provided by Yamanaka. The major changes from the design concept model are as follows:

1. The joint section of the socket was redesigned based on the use of the internal adaptors.
2. The outer shape of the socket was modified at the bottom of the joint section, which now stretches along the shape of the leaf spring.
3. The internal structure has been improved to increase structural strength.
4. The form of the outer trabecular structure was modified greatly.

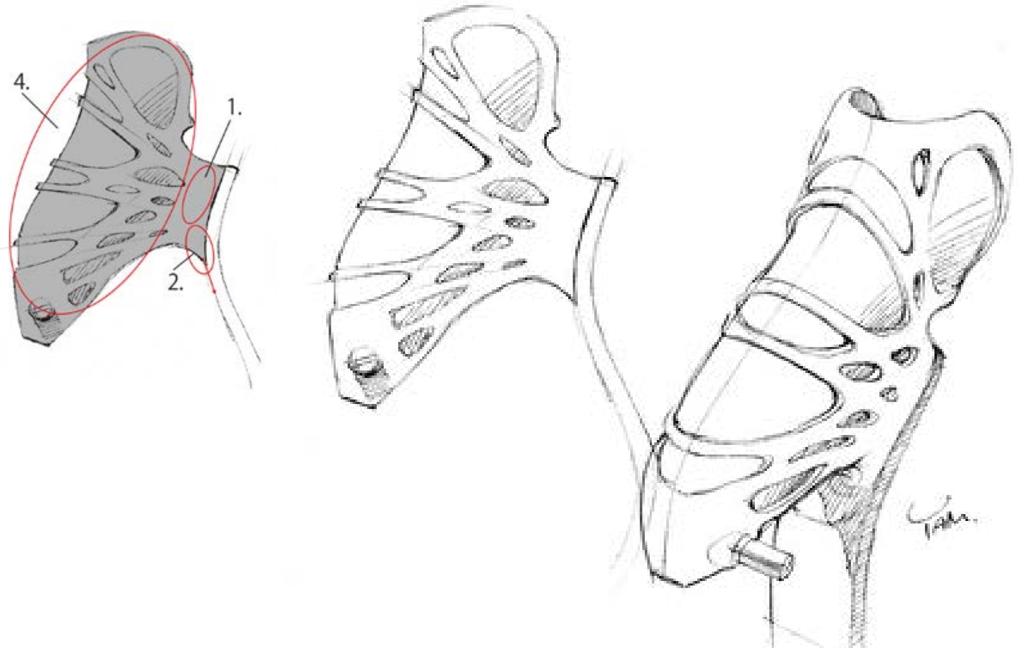


fig. 21 The design sketch

Regarding the item 2 above, it was estimated that the stretched section would function as a strength structure when the prosthetic leg is compressed downward. Simultaneously, this modification aimed to enhance a sense of unity of the appearance of the prosthetic leg when it assembled. For item 4, the number of holes on the outer trabecular structure was reduced to reinforce the strength. Although the lightweight properties of the socket are significant, the design prioritizes reliance on strength at first. Fig. 22 and 23 indicate the results of CAD modeling and the appearance of the socket after the production.

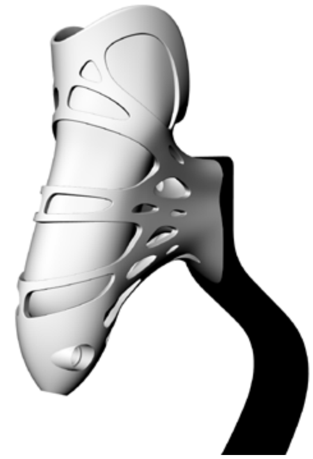


fig. 22 The CAD model

fig. 23 The manufactured socket

The strength experiment for the running test model

A strength experiment for the running test model was conducted. The universal strength testing machine Autograph AG−IS (Shimadzu Inc.) was used for the test. Two pieces of jigs were used in the test (fig. 24). One is made of aluminum and designed to hold the socket vertically on the machine. The other is made by AM and its shape is designed to fit into the socket. The result of the experiment is shown in fig. 25 underneath. It has been confirmed that the running test model can withstand a load of over 17kN (176,594N), satisfying the strength benchmark that was originally targeted.

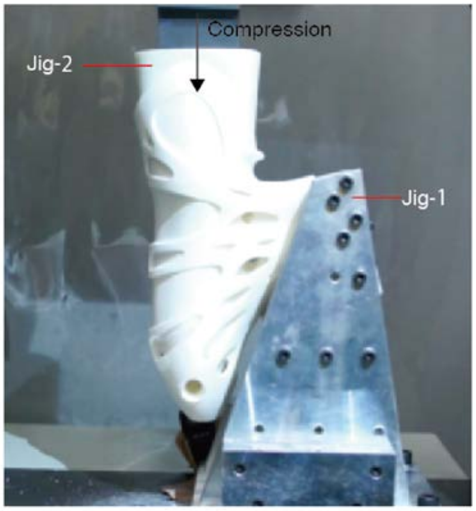


fig. 24 The strength experiment

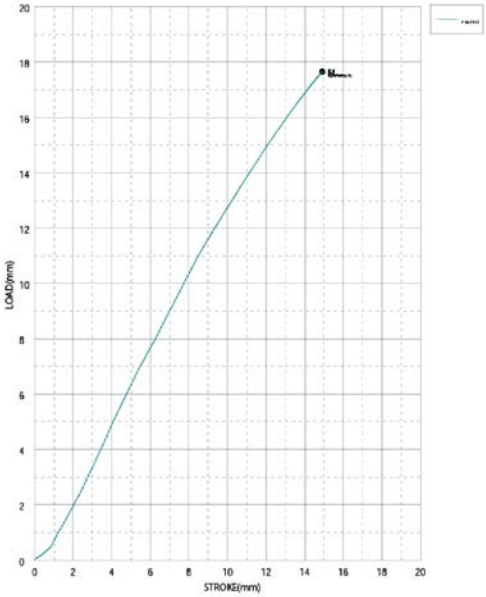


fig. 25 Load vs stroke trace,

X-axis refers stroke, Y-axis refers load

The primal running test

The primal running test was conducted by using the running test model prosthetic socket. Scenes of the test are shown in fig. 26. The main purpose of this test was to get feedback from the athlete. Although the structural strength of the socket itself was certified in a previous compression test, the reliance of the locking mechanism that fixes the residual limb and the socket together was not confirmed to be completely reliable. Therefore the maximum speed was set at a jogging pace. The knowledge that we have obtained through the test is listed and categorized as follows:

Weight (fully assembled, include the leaf spring)

- Existing RSP 1449g
- AMed RSP running test model 1505g

Structural issues

- There is no problem with either the strength or bending stability.
- No deformation around the aluminum adaptors was seen.
- The locking mechanism between residual limb and socket can be seen as lacking reliability.

Friction of surface

- The socket surface has a lot of friction; it may be uncomfortable while attaching the prosthesis.
- The end of the residual limb felt uncomfortable when attaching the socket. It could become painful for the amputee.

The center of gravity:

- Is behind the center of the socket and affects the user’s notion of speed, making the user feel as if they were running slower.

Appearance

- Organic styling and characteristics.
- Coloring the external surface would be ideal for personalization purposes.
- Giving it an agile look would be preferable.

fig. 26 The primal running test

Conclusion

A new design concept for RSPs was established. The concept enables to manufacture both functional and aesthetically pleasing prosthetic socket by utilizing the benefits of AM technology. We succeeded in manufacturing a prosthetic socket that can be used for the primal running test by using a Nylon 12 based LS type AM machine.

Remaining issues

One of the characteristics of objects that are manufactured by AM is the unevenness of the surface. The surface has a lot of friction and it could become a negative factor for the user. In order to improve the product value, new methods should be established for an effective treatment of the rough surface. It is also desirable that the method can cope with complex design forms.

Regarding the locking mechanism between the socket and the amputee's residual limb (fig. 26 left picture), the use of existing metal parts cannot be avoided. Investigation for joint methods that are more supportive and durable than the current options should be required in terms of size calibration and material strength.

The purpose of this study is to provide mass-customized products for more people rather than providing tailor-made products for specific persons. As a next phase of this research, we have planned the development of a CAD software that is able to apply the method of design obtained by this work to prosthetic limbs. It is desirable that the software can be able to tighten cooperation among designers, prosthetists and Computer Aided Engineering (CAE) technologies so that the beautiful and functional prosthetic legs can be designed in time and cost-efficient operations.

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