33rd Annual International Conference of the IEEE EMBS
Boston, Massachusetts USA, August 30 - September 3, 2011

A new proposal of tailored bioinstrumentation using rapid prototyping and three-dimensional CAD

- First trial to develop individually designed cuff-units for continuous blood pressure measurement -

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Abstract—**The concept of tailored bioinstrumentation using rapid prototyping and three-dimensional CAD (3D-CAD) was proposed. This concept is to make individually designed and fabricated sensor unit to attach human body. Within the proposed concept, cuff-units for continuous blood pressure measurement were individually designed using 3D-CAD and fabricated automatically. As the result, blood pressure wave forms can be obtained using the finally developed cuff units. Using rapid prototyping device, the design and fabrication process were accelerated without any artisan-like high skilled persons.**

I. INTRODUCTION

Recently, the importance and significance of wearable monitoring and/or ubiquitous monitoring have been received additional attention. Reasons behind this should be the increase in the number of elderly person, need of prevention of lifestyle rerated diseases, request of halt growth in medical spending, and so on. For wearable/ubiquitous monitoring, many novel ideas have been attempted, reported and published. Needless to say, significant results have been achieved in this field, and then study of this field should be expected to continue and provide many results.

Besides those attempts, we have been focusing a novel methodology to design a wearable/ubiquitous monitoring instrument, and attempting a new point of view to be re-acknowledged in these years. Our new proposal is based on following points.

1) The sensor part that attached on human body should be tailored to individual patients (individually designed for each subject).
2) The tailored sensor part should be designed by a not highly skilled artisan.
3) The tailored sensor part should be manufactured in an easy way.

For achieve those points/requirements, we considered that recently greatly expanded rapid prototyping techniques combining with three-dimensional CAD (computer aided design) can be used. In this paper, we would like to propose a tailored bioinstrumentation with using rapid prototyping and three-dimensional CAD and attempts to show the first trial under the proposed concept; developing an individually designed cuff unit for continuous blood pressure measurement.

II. PROPOSE OF TAILORED BIOINSTRUMENTATION

A. Why tailored?

Almost of wearable/ubiquitous monitoring are considered as an extension of traditional physiological measurement "*implicitly*." In other words, design strategy of wearable/ubiquitous monitoring devices mainly consist of miniaturization of traditional devices, addition of function for battery-operation, bolt-on BAN (body area network) and/or LAN (local area network) transmitter for wireless communication and so on. These directions can be considered as reasonable especially in early stages of the development, like as feasibility study phase and early development phase.

However, in the days ahead, wearable/ubiquitous monitoring has to be evaluated in an actual situation, daily living during 24/24H. From this viewpoint, almost of published attempt of wearable/ubiquitous monitoring appears lack an important point; that is a tailored sensor part design. Because wearable/ubiquitous monitoring has to be used everywhere and all time, the devices have to be designed to perfectly fit the subject to be monitored. For this, the sensor part that is attached directly to a human body has to be designed for each person, each subject. The researchers in this field should

Manuscript received April 14, 2011. This work was supported in part by the Japanese Ministry of Health, Labor and Welfare under the Health Labor Sciences Research Grant (H21-Trans-General-013), Japanese Ministry of Education, Culture, Sports, Science and Technology under the Grand-in-Aid for Scientific Research (A) 21240047, 2010 and 2011 and Japan Ministry of Internal Affairs and Communications under the Strategic Information and Communications R&D Promotion Programme (SCOPE; No. 102305004, 2010) and also The Second Stage of the Knowledge Cluster Initiative Project (Hokuriku Innovation Cluster for Health Science), Japanese Ministry of Education, Culture,Sports, Science and Technology.

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remind proverbs; *"Every shoe fits not every foot"* and *"All feet tread not in one shoe."*

Here, we can discuss a comparison between dental field and wearable/ubiquitous monitoring. Artificial tooth and dental implant are designed individually, *id est* tailored. This is a common practice. When it is thought carefully, this can be because a person has a sense in his/her mouth anytime. Individually made artificial tooth and dental implant is for not only the masticatory function but also reducing a feeling of strangeness. As with the artificial tooth and dental implant, wearable/ubiquitous monitoring devices should be designed to reduce a feeling of strangeness during attaching the devices and the sensor part of them. For this, the devices and the sensor part should be tailored to individual patients.

Next, we can think about the design and fabrication of the sensor part. In a laboratory based study, a great success of a very high skilled manufacturer (like an artisan) might be expected. He/her could make a so sophisticated component of devices. At least, those component and devices could be worked in the laboratory based study. However, in an actual situation, those artisan-like high skilled manufacturers should not be expected. The high skilled manufacturer dependent strategy should be abandoned. We have considered that the sensor parts should be designed by not high skilled peoples and those parts should be manufactured in an easy way. To meet those requirements, the rapid prototyping techniques and three-dimensional CAD should be considered as employed.

B. Rapid Prototyping

Rapid prototyping is defined as the automatic construction of physical objects with using additive manufacturing technology that creates an object by addition of many thin successive layers. Rapid Prototyping also includes a group of techniques aiming quick fabrication of a relatively small object/model with using three-dimensional computer aided design (3D-CAD), solid free-form fabrication/manufacturing and computer automated manufacturing. A number of different rapid prototyping techniques have been attempted and several of them have been available. For example, some rapid prototyping devices use melting or softening material to produce the layers, others use liquid thermosetting polymers and so on. This technique has been rapidly commercialized in these 20 or 25 years. Finally, many rapid prototyping machines can be found and available in the market.

The reasons of rapid prototyping can be considered as follows;

1) To decrease communication problem between a designer and a manufacturer.
2) To decrease total development time.
3) To decrease costly and/or fatal mistakes in design and manufacturing.
4) To increase chance of evaluation in the real world; we can meet many prototype easily.

These features of rapid prototyping can bring an easy repetition process in design and fabrication of components and this allows a good design and a good parts, components and devices with out artisan-like high skilled person.

Fig. 1 Employed rapid prototyping device

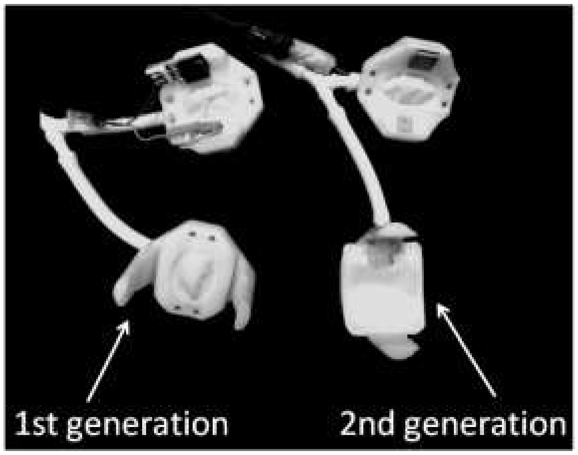
We have introduced the rapid prototyping with 3D-CAD strategy to fabricate tailored wearable/ubiquitous bioinstrumentation, and the first trials of it are described in later part of this paper.

III. First Trials of Tailored Bioinstrumentation

To demonstrate the described concept, development of tailored (individually designed) cuff-units for continuous blood pressure measurement was attempted as the first trial. For the means of continuous blood pressure measurement, a non-invasive instantaneous BP measurement called the "volume-compensation method" that was proposed by our group and was based definitely on the arterial tube law have been employed [2 - 4]. While partial pressurization cuffs have been adopted so as to avoid venous congestion to achieve a long-term measurement during recent years [5 - 9], the designs of them are not so simple. As a matter of fact, there have been many failures and there must be a number of repeat evaluations. Then, those developments can't avoid becoming a time consuming process and have been considered as a bottleneck of studies. Additionally, as described, the cuff part that attach on the human body should be individually designed and fabricated in an easy way. Against this background, we have been attempted to introduce rapid prototyping with 3D-CAD to make tailored cuff units.

A. Rapid prototyping system

The uPrint Personal 3D Printer (Stratasys Inc., Minnesota, USA) was used as a rapid prototyping device (see Fig.1). This uPrint 3D Printer is based on their FDM (Fused Deposition Modeling) technology to make an object with a thermoplastic material. To design of parts/components, a 3D CAD software Google Sketchup (Google Inc., California, USA) was used. The design by the 3D CAD software can be exported to STL format files whose format is widely used for rapid prototyping and computer-aided manufacturing to describes the surface geometry information of a three dimensional object.



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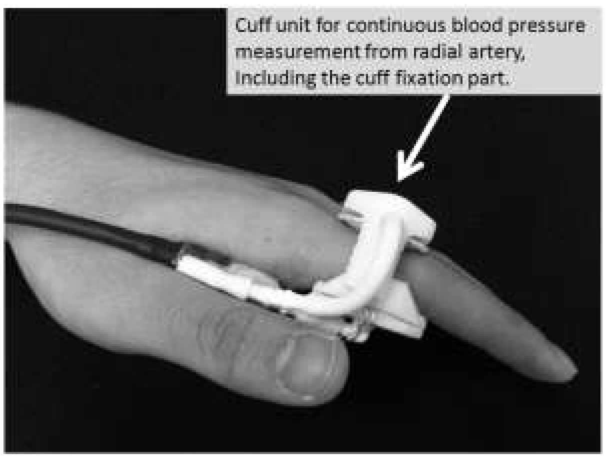

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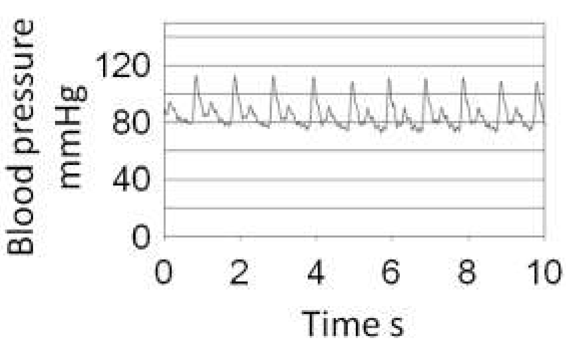
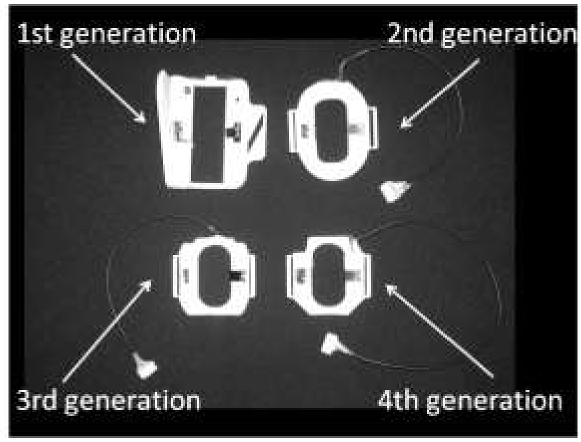


(c)

Fig. 2 Tailored cuff unit for continuous blood pressure measurement from radial artery of an index finger. (a) Four generations of tailored cuff fixation parts, the fourth one is the final version. (b) Non-invasive blood pressure measurement from radial artery. (c) Obtained blood pressure waveform.



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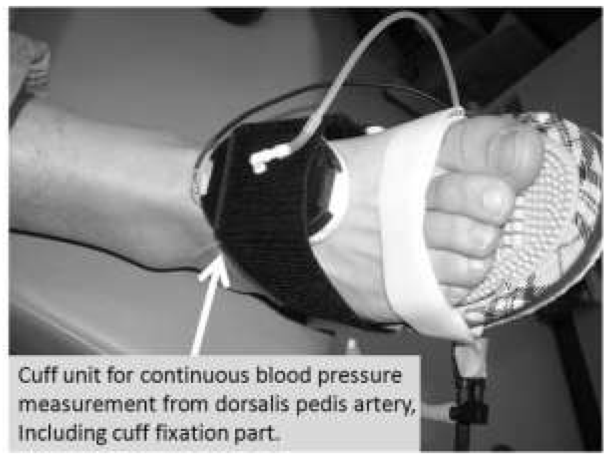

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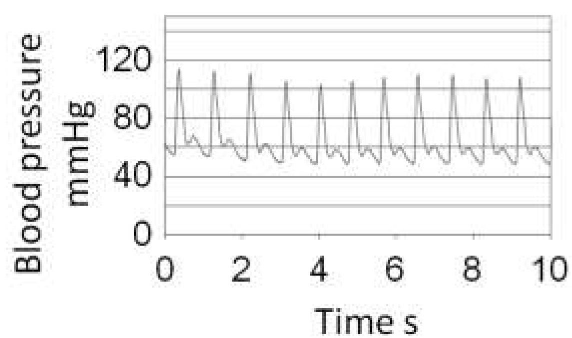

(c)

Fig. 3 Tailored cuff unit for continuous blood pressure measurement from dorsalis pedis. (a) Four generations of tailored cuff fixation parts, the fourth one is the final version. (b) Non-invasive blood pressure measurement from dorsalis pedis. (c) Obtained blood pressure waveform.

B. Tailored cuff unit for continuous blood pressure measurement

Two types of cuff unit were attempted to be designed and fabricated. The first one is the cuff unit for continuous blood pressure measurement on a finger to obtain blood pressure from radial artery. The second one is the unit for measurement on a foot to measure blood pressure from dorsalis pedis artery. In this time, the cuff and sensor fixation parts of cuff units were attempted to be designed and fabricated. The design and fabrication process were done by not high skilled persons.

Fig. 2 shows developed cuffs (including the cuff and sensor fixation part) for finger and finally obtained blood pressure waveform. In Fig. 2, two generations of cuff are demonstrated. Although there was only minor change between the first generation and second generation, the cuff has to be re-designed and totally fabricated again. Using rapid prototyping, this re-design and re-fabrication were done very quickly (about two days) and fabrication process was totally automated. This cuff unit is designed for a subject individually. Fig. 3 shows developed cuff units (including the cuff and sensor fixation part) for dorsalis pedis and resultant blood pressure waveform. In Fig. 3, four generations of cuff are demonstrated. Between the first generation and second generation there was big difference, but after that, there also were only minor changes between generations. In this case, re-design and re-fabrication processes were accelerated and considered as not time consuming with using rapid prototyping.

IV. Discussion

We have already proposed physiological measurement using sensors that are immersed in articles of furniture (bed, bathtub, toilet and so on) to obtain physiological data without any disturbances on daily living [10]. The newly proposed tailored bioinstrumentation is along same vision that bioinstrumentation executed outside of a hospital and laboratory should not hinder subject's behavior and it is ideal to measure without subject's awareness of the sensor. This viewpoint should be important in physiological measurement in various situations.

The concept of ambulatory physiological measurement has been expanded and recently many wearable/ubiquitous measurements have widely attempted with using small and lightweight devices. We would like to propose that the next noteworthy point can be tailored design.

This concept can be easily enhanced to another area. Foe example, we have been attempted a novel endoscope for visualization of a great artery with using a saline jet. To develop an optimized the jet nozzle, the rapid prototyping and CAD was also used and the development period was drastically shortened. Fig. 4 shows the developed jet nozzle. In future, we'll attempt to an endoscope design for fitting in each subject.

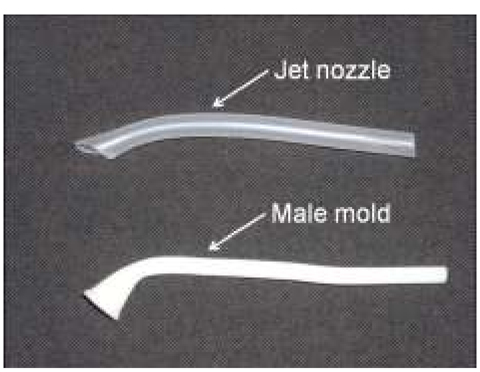

Fig. 4 Jet nozzle made by rapid prototyping and its male mold. The male mold was fabricated by the rapid prototyping device.

V. Conclusion

The concept of tailored bioinstrumentation using rapid prototyping and three-dimensional CAD was proposed. Under the concept, cuff-units for continuous blood pressure measurement were individually designed and fabricated. Using rapid prototyping device, the design and fabrication process were accelerated without any artisan-like high skilled persons.

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