A NOVEL APPROACH FOR ANKLE FOOT ORTHOSIS DEVELOPED BY THREE DIMENSIONAL TECHNOLOGIES

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Abstract. This study presents a novel approach for testing mechanical properties of medical orthosis developed by three dimensional (3D) technologies. A hand-held type 3D laser scanner is used for generating 3D mesh geometry directly from patient’s limb. Subsequently 3D printable orthotic design is produced from crude input model by means of Computer Aided Design (CAD) software. Fused Deposition Modelling (FDM) method in Additive Manufacturing (AM) technologies is used to fabricate the 3D printable Ankle Foot Orthosis (AFO) prototype in order to test the mechanical properties on printout. According to test results, printed Acrylonitrile Butadiene Styrene (ABS) AFO prototype has sufficient elasticity modulus and durability for patient-specific medical device manufactured by the 3D technologies.

1. Introduction
Orthosis are assistive medical devices to support patients’ biomechanical needs and contribute their quality-of-life as a result of aging and accidents. Each orthosis is used to control extremity to recover functionality and named according to location of injured body part. The most common orthosis used in orthopedics can be classified as illustrated in Figure 1.

Figure 1. Orthosis classification in orthopedics
AFOs are used to control motion of the ankle and prevent deformities. AFOs can generally be used for following purposes: brace weak limbs, grasp ankle & foot in the right position and correct the foot drop. Since the users have different sizes of ankles and different types of deformities, an AFO must be produced to match in size to the patient. Mass production AFOs may not suitable for each patient and may deteriorate the illness. Considering these factors, 3D printing and 3D scanning technologies are of great importance for producing individualized biomedical equipment [1].

1.1. Scanning Process

Nowadays there are numerous 3D scanning technologies such as laser triangulation, structured light, photogrammetry, and contact and laser pulse. These technologies digitize the real objects to form the raw geometry. 3D scanning is a process to obtain the geometry of an object by using 3D scanner. The resolution of 3D scanning is as important as the 3D scanner type and hardware.

3D scanning technologies applied outside of the real objects are generally used in industry, medicine, military and education. These technologies have promising solutions for medical needs such as anatomical models, biocompatible implants, orthotic & prosthetic models, plastic surgery, biomedical engineering and tissue engineering [2]. 3D scanning can be classified as explained in Table 1.

| Field      | Section                      | Solution                                |
|------------|------------------------------|-----------------------------------------|
| Industry   | Reverse Engineering          | Remanufacturing old parts               |
|            | Rapid Prototyping            | Prototype manufacturing                  |
| Aerospace  |                              | Part replacement                         |
| Medicine   | Orthopedics & Prosthetics    | Patient-specific medical devices         |
|            | Anatomical Bio Models        | Anatomical to assist-surgical models     |
|            | Plastic Surgery              | Prediction-planning plastic surgery      |
|            | Implants Dental              | implants                                 |
| Military   | Mission Planning             | Terrain-building reconstruction           |
|            | Crime Scene                  | Criminal investigation                   |
|            | Prototype Manufacturing      | Gun-vehicle parts                        |
| Education  | Training                     | Educational models                       |
|            | Research                     | Experimental studies                     |
| Art        | Architecture                 | Environmental-heritage                   |
|            | Fashion                      | Clothes-shoes                            |

New 3D scanners can create mesh geometry of objects directly with real-time scanning. However most of the 3D scanners used in medicine still require manual surface reconstruction to finalize the missing meshes. Some details on the surface can be distortable and pattern failure can occur in raw model after reconstruction process. In order to prevent this distortion, 3D scanning process should be carried out in real-time with relevant types of 3D scanners. Thus designers can achieve more precise results.

1.2. Printing Process

3D printing is generally known as Rapid Prototyping (RP) or Additive Layer Manufacturing (ALM). RP and ALM are the fabrication approaches that build two dimensional (2D) layers to form almost any shape of three dimensional (3D) solid objects. A 3D printer can be accepted as a type of industrial robot that prints almost anything from a toy or a gun to manufacturing prototypes with outstanding resolution and surface quality. Prototype manufacturing especially in conventional methods is time consuming, expensive and requires specific skills which few engineers have. However, 3D printers reduce time and cost of designing new prototypes [4]. In general, 3D printing procedure of any object including AFOs is illustrated on Figure 2. A solid object can be fabricated by utilizing a 3D printer in four particular stages to be specific; demonstrating stage, cutting stage, printing stage and completing stage.
3D printers are quickly creating advancements and progressively being utilized as a part of a few fields, for example, car, assembling, workmanship and building. A considerable amount of studies have been completed on the execution of car, assembling, workmanship and building fields [5]. Notwithstanding, utilization of 3D imprinting in medicinal division is toward the starting stage and has an energizing vision that will bring numerous open doors for humankind [6, 7]. As of not long ago, extremely constrained executions utilizing 3D printers have been led on biomedical division. This usage can be given as titanium pelvis embedded, bring down jaw transplant, plastic tracheal prop and prosthetics utilized for debilitated creatures [8, 9]. Figure 3 shows real-time scanning in progress of foot deformities in patients with the help of human scanner.

2. Methodology
In this study, a hand-held type 3D laser scanner with structured light scanning technology is used to obtain mesh geometry of the patient’s limb. This scanning technique is an automotive process of attaining digital input data of patient’s anatomy. The 3D scanner is rotated manually around patient’s limb to create the template model in just one minute. This raw template is used directly for the modelling process of personalized orthotic design. This approach can be accepted as a time-saving approach when digitizing.

3. Results
Poly (Acrylonitrile-butadiene styrene, ABS) is a popular thermoplastic used widely in industry and science. It has some important specialties such as high impact strength, easy processability, smooth surface characteristics, dimensional stability and low price. ABS is also important for patient-specific medical orthosis due to its mechanical properties mentioned above and easy printability in 3D printers. Mechanical properties of an AFO prototype produced from ABS by means of a 3D printer are tested first time in the literature. Dog bone samples have been printed by a 3D printer for tensile test to analyse material strength of AFO prototype. Figure 4 illustrates dog bone samples that have been produced with the same printing parameters of AFO due to having meaningful results. The test results present patient-specific printing parameters that are very useful for computing material cost and measuring material strength. When external force is exerted on a material, they change shape and size. ABS is stiff, rigid and tough material. It provides the necessary support under a certain load because of having high impact resistance. A tensile test is performed in order to identify the resistance of the 3D printed AFO prototype. At his tensile strength, the AFO prototype has maximum %6.8 strain. At his tensile strength, the AFO prototype has maximum %6.8 strain. If the applied tensile stress goes beyond this peak value, the material has permanent deformation on its polymer structure and finally material is ruptured. The same AFO prototype produced in this paper is experimentally applied to an end-user with 65 kg weight male in order to observe durability.
Table 2. Tensile and Charpy impact test results

| Test Type  | Parameter     | Value          |
|-----------|---------------|----------------|
| Tensile test | Tensile strength | 38.4 MPa       |
|           | Max strain %  | 6.8            |
|           | Elasticity modulus | 767.6 MPa  |
| Charpy test | Sample        | 13x80x2 mm     |
|           | Energy        | 14.96 kJ/m²    |

The tensile and charpy impact test data of AFO prototype is given in Table 2. The sample ABS material (Figure 5) having dimensions of 13mm (width) x 80mm (length) x 2mm (height) is ruptured when 14.96kJ/m² impact is exerted on its surface. The AFO made from ABS has sufficient elasticity modulus for patient-specific medical device manufactured by means of three-dimensional technologies. In addition to tensile and charpy impact test, a static load test is applied on the surface of medical orthosis by means of Universal Test Machine to observe compression durability. In order to perform this test, AFO prototype is first cut by an electrical saw and then mounted on the test machine. Figure 6 illustrates the prepared orthosis for compression test. Two different tests are performed in order to have more reliable results First test: A load is applied to the inner surface of AFO prototype up to 5 kN with 0.1 kN/s increment. Second test: A load is applied to the same surface of AFO prototype up to 15 kN with 0.1 kN/s increment. Figure 6 shows that 3D printed ankle foot orthosis for foot deformities patients. Successful results are obtained from these tests such that AFO prototype withstand loads without deformation. Figure 7 illustrates the compression test versus load and time.

4. Discussion
Recovery process can take several weeks to several years depending on the damaged tissues or disease. As 3D technologies are time and cost saving when manufacturing, it is important to analyze mechanical properties of printed medical orthosis. These test approach can show the mechanical properties of adhesion. The adhesion is depending on the slicing parameters, printing parameters and the 3D printer. Thus, these tests are necessary to obtain results of printed medical orthosis. It is important to know the quality of manufactured medical orthosis by means of three-dimensional technologies. Solid Works simulation tests also can be applicable at this stage.

5. Conclusion
Printing parameters such as layer height and infill rate plays crucial role to determine the mechanical properties of medical orthosis. Four different tests namely tensile test, charpy impact test, static load test and hydraulic press test are performed to analyze the AFO prototype made from ABS. The tests and its
results can be summarized as follows: A tensile test is carried out for identifying the resistance of AFO prototype. According to this test, maximum %6.8 strain is observed when 38.4 MPa tensile strength is exerted on the AFO prototype. Charpy impact test is performed for observing durability of AFO prototype. According to this test, when 14.96kJ/m² impact is exerted on the surface of sample ABS material with dimensions of 13mm x 80mm x 2mm, a certain rupture is occurred on its surface. Two static load tests are performed to measure durability of orthosis and obtain more reliable results. In order to perform this test, AFO prototype is first cut by an electrical saw and then mounted on the test machine. A load is applied to the inner surface of AFO prototype up to 5 kN with 0.1 kN/s increment as a first test. Then a load is applied to the same surface of AFO prototype up to 15 kN with 0.1 kN/s increment. Successful results are obtained from these tests without deformation. Hydraulic press test is applied on the orthosis to observe maximum durability. Maximum 10 tons load is applied to the AFO prototype which passed again successfully without any deformation.

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