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Design of 3D-printed Orthosis to assist patients with wrist fracture

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Abstract — A normal POP cast used for healing a limb fracture is an age-old technique, without many innovations in its practice and methods. While we all are moving ahead with other advancements in the medical field, POP casts are still the same since their invention in 1839. These casts have many known drawbacks such as heavy weight, nonwater-resistant, and prolonged usages have resulted in skin irritation or rashes and in some cases even major skin problems like gangrene.
The objectives of this study were accomplished through the creation of a functional 3D hand parametric hand model, the use of the functional 3D parametric hand support as a pattern to create a customized approximation of 3D hand model, the study also aims to limit movement to relieve pain and discomfort by restricting the movement of the wrist with the use of the orthosis design, the construction of a 3D printed wrist support orthosis, and the reporting of a case study on the usability. This study demonstrates the viability of optimizing the reverse engineering of a wrist support orthosis using a 3D hand parametric model.

Keywords—Orthosis, Additive manufacturing, Hand Orthosis, orthotic devices, fused deposition modeling, 3D printing technology.

Nomenclature—
3D Printing- 3 Dimension Printing
POP- Plaster of Paris
PLA- Polylactic Acid
FDA- Food and Drug Administration
OA- Osteoarthritis
CBT- Cognitive Behavioral Therapy
CMC- Carpometacarpal
CAD- Computer-Aided Design
STL- Standard Triangle Language
FDM- Fused deposition modeling
AM- Additive Manufacturing
ABS- Acrylonitrile Butadiene Styrene
PC- Polycarbonate
PA- Polyamide
PS- Polystyrene

I. INTRODUCTION

An orthopedic cast is a shell, frequently made out of Plaster of Paris, it incases a limb to stabilize and hold a broken bone in place until healing is confirmed. The limitations of a normal cast over a 3D Printed cast are numerous aside from the fact that they are unpleasant to look at and very uncomfortable to wear. Applying a plaster cast can be a long, laborious, and sometimes messy process. It requires a lot of careful and precise measuring, and the manual application of bandages can be painful if not done carefully. One significant drawback of plaster is that it is not breathable. The solid plaster prevents air contact with the skin. This can lead to blocked pores, and some patients can develop nasty skin infections in wounds. What's more, the constant warmth, sweat, and pressure can cause very uncomfortable itching. Another frustrating issue for cast-wearers is you cannot get it wet. Be it in the rain, the bath, or the shower. You have to take extra care to avoid soaking it as this can affect its strength. It will break down if wet, interrupting the healing process. The plaster casts can be of considerable weight, which may result in restricted or uncomfortable moments.
The 3D Printing process is done using PLA material, which is a type of plastic that is obtained from renewable and natural raw materials such as corn. PLA is hypoallergenic and safe, such that it has been approved by the FDA. Its non-toxic composition makes it useful in the medical and healthcare industry. Between the 3D Printed cast and the patient's skin, there lies a white cast padding. which is non-woven and is made using viscose fibers. It brings comfort to the patient when using the cast.
There are many benefits for a 3D printed cast, such that it enhances the faster and easy healing of the injury while keeping the skin of the patient. Once the cast is 3D Printed, it can be quickly and easily fit in a matter of seconds with a couple of clips or strings to hold it in

place. Removing the cast is similarly simple, and does not require dangerous electric saws to cut away layers of hardened plaster and fiberglass. The entire process is safer and more streamlined. The plastic is built with large open sections, with the plastic struts providing the necessary structure without completely covering the arm. The material is porous and allows easy air flow through it. This is one of the biggest factors contributing to the higher comfort rating of 3D Printed casts reported in medical studies. The 3D casts can be custom-designed. The structure can be designed to add strength to the specific areas that need support, and sparser elsewhere. This personalized approach maximizes recovery speed and comfort for each patient. 3D Printed casts are made using waterproof plastic so you don't have to hold your arm or leg outside the bath in order to wash. You can go swimming wearing it, so the fun doesn't have to stop either.

Considering the many advantages of the 3D Printed Cast over Normal Cast, they have been picking up worldwide.

II. LITERATURE SURVEY

Hand Orthosis

This paper, assigned to Gizmo Medical LLC., is a continuation of Butler et al filed a patent back in 2017. It features a hand brace design that limits motion to avoid hyperextension. The design makes use of light yet durable materials to ensure comfort and protection. The hand orthotic is designed to help alleviate the stress of a person's hand. Stress like this could come from hand injuries or ADLs.
[3]

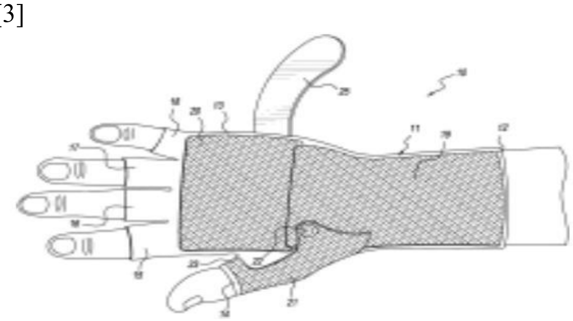

Fig.no.1: Hand Orthotic[3]

3D-printed Splint and Cast

This paper, filed by Rivlin et al in the year 2017 and assigned to Dimension Orthotics LLC, is a two-piece 3D-printed splint. The splint is composed of an upper and lower part which are joined together to enclose the patient's arm. The goal is to boost production while also negating some of the downsides of using traditional casts and splints, which may cause irritation in the user's skin when worn for longer periods of time. Traditional splints also lack the customizability found in 3D-printed designs. The usage of polymer for the production provides a slightly better elasticity to adjust to the changes that may occur, while also providing stiffness to limit the hand's movement. This also allows the splint to be more versatile as the usage of plastic makes it more capable of being weathered or washed as compared to traditional designs. [4]

Nature of the Problem

The study of Fucher et al (2020) tackles the actual application of the 3D printing process in creating an assistive device, namely an exoskeleton. This technology has been of great use in orthopedics, specifically in surgical procedures and prosthetics used by amputees. Furthermore, the study explored the impact of allowing prosthetics to be more aesthetically pleasing and its effect on the amputee. The main focus is more on the social impact of prosthetics on the patient. In this case, 3D printing is used in providing coatings or covers on existing prostheses, serving more as accessories. [5] Exoskeletons were briefly mentioned in the paper. These devices serve as assistive devices on an affected limb rather than a replacement for a missing limb. It is an external and non-invasive device, and is mainly used in restoring movement functions and rehabilitations. Patients with diseases such as temporary paralysis from spinal cord trauma and encephalic vascular accident patients would benefit the most from this.

There are other types of treatment for musculoskeletal diseases besides the usage of physical supports. Varga, Stoicu-Tivadar, and Nicola (2021) studied one unconventional way of rehabilitation of patients with rheumatoid arthritis.

The disease is described to affect the quality of living of the affected people as well as shortening their life expectancy; the disease is prominent in people who are around 40-60 years of age. Rheumatoid arthritis (RA) is inflammation of the joints, most prominently the joints of the hands. [6]

III.PROBLEM STATEMENT

This project is titled "3D printed orthosis design." The purpose of the present study is to define and describe the new product that has been developed. This product aims to present a new concept of 3D printed wrist orthosis. The aim of this project is to create a product which is able to solve medical problems such as tendinitis, carpal tunnel syndrome, wrist sprains and so on. Nowadays, these problems are affecting a large number of the population.

One of the most important aspects to consider is the aesthetics. As it is known, an orthosis is something that can not be hidden. This is why it was wanted to look for an innovative product that is the same as simple in order to anybody who will wear it without any qualms.

As said before, the production method will be the additive manufacturing which not only means an aesthetic improvement but it will be much easier to use and to place, besides allowing the doctor a better help for the recovery of the patient. It also will avoid problems that the traditional plaster had, such as sweat, itching or the inability to take a shower…

Furthermore, 3D printing improves the quality of the pieces, speeds up the production process and advances in the reduction of costs which is a very important factor of society nowadays. So one of the requirements to achieve is to design an affordable orthosis for everyone.

IV. METHODOLOGY

A] Design Process:

The measurement of the body part is the first stage in creating a traditional orthosis. Once this is completed, a negative impression is made using a plaster bandage. The plaster is gently sliced or sectioned and removed when it has dried, maintaining the shape. Sanding is used to finish smoothing the affirmative plaster model's surface.

Fig.no.3: Conventional Method

In the field of health, 3D printing is now a practice. Because of the development in technology, we are now able to develop solutions that are developed specifically for patients. We need to examine how orthoses are made using both conventional and 3D printing techniques in order for this to be feasible.

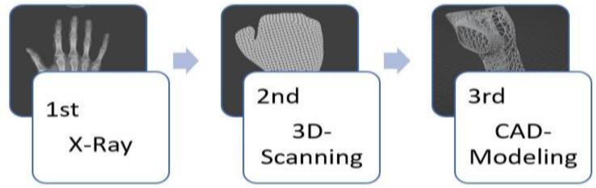

Fig.no.4:Design Process

The evaluation of the fractured person's X-rays is the first step in the additive manufacturing process for making an orthosis. Next, a three-dimensional scan of the area is generated using a 3D scanner. A 3D scanner or medical imaging device records image data with 3D spatial information of the limb. The contralateral side of a fracture is frequently scanned and used as a mirror image.

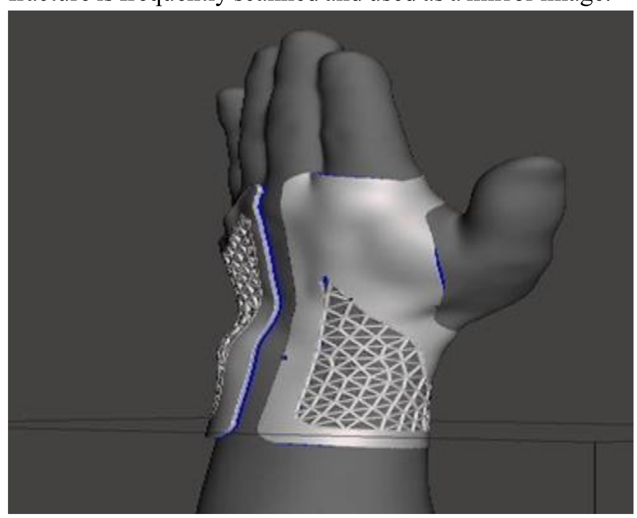

Fig.no.5 CAD modeling

After that, CAD software is used to process the orthosis model while taking the patient's limb's dimensions into account. With the use of computer aided design and reverse engineering software, the brace is further refined.

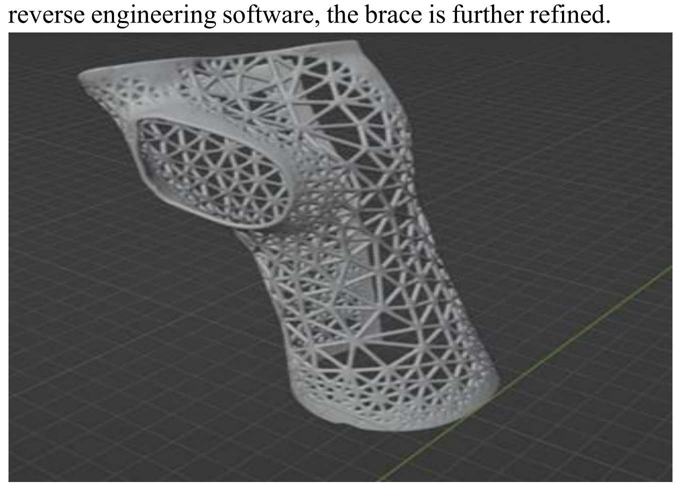

Fig.no.6: 3D model Splints

Finally, the bespoke structure is created using 3D printing technology. An orthosis is entirely tailored for each patient once it has been created, and all that is left to do is for the specialist to place and modify it on the patient. Printer processes use additive manufacturing methods. Design goes into the mesh and the mesh holes. Design additives can also be created as part of this stage, if desired. This may only involve pressure padding, but sensors, nerve, muscle, or bone stimulators, or infrared spectrum photodiodes (used to track changes in skin pigmentation and damage over time) may also be incorporated into the brace's construction. For 3D printing, the finished design is saved as a STL format file.

B] Material Selection:

Since having been said, the orthosis can be constructed of various materials, with each other, metal, plastic, neoprene, leather, synthetic fabrics, or any combination of these, there is a huge variety in the materials from which it can be made, from conventional plaster casts to the material with used the three-dimensional (3D) printing technique, also known as additive manufacturing (AM), whose use is growing explosively. However, in additive manufacturing, the part's shape is being established at the same time as the material properties. Although the raw material (i.e The chemical composition of the polymer, the size and distribution of metal powder particles) has an effect, process parameters also have an impact on elements such as the final part's strength, ductility, porosity, and surface finish. This presents opportunities as well as additional challenges that are specific to additive. It is feasible to deliberately and accurately regulate the material's properties in particular parts of the part by introducing attributes like porosity, stiffness, or flexibility when the material's properties are determined alongside the geometry.

Fig no 7: Using Plaster (POP)

The most frequently used metals for joint components, uprights, sprints, and bearings are stainless steel and aluminum alloys, which are adjustable but heavy and costly. In filament-driven systems, thermoplastics like PLA and ABS are some of the most often used materials, although high-performance materials like Polyetheretherketone (PEEK) and Polyetherketoneketone (PEKK) are also gaining popularity. PLA is common in manufacturing.

C] Manufacturing:

The traditional orthosis technique takes a lot of time, requires special skills, and is not always successful in producing a good orthosis.

Additionally, it is frequently difficult to satisfy all of the patient's needs, requiring changes to both the method and the result. In order to get over these restrictions and enable new devices in terms of fit and usefulness, additive manufacturing (AM), also known as 3D printing, fast prototyping, or solid freeform production, uses a sequence of submillimeter layers to build items.

AM can be used in a variety of ways to enhance the quality of life for someone who must wear an orthosis.

Fused deposition modeling (FDM): FDM is a method of additive manufacturing (AM) that is frequently used for applications in modeling, prototyping, and production. A plastic filament or metal wire is unwound from a coil and provides material to make a part in FDM, which operates on a "additive" basis by laying down material in layers. There are numerous materials with varied strength and temperature trade-offs, including Acrylonitrile Butadiene Styrene (ABS), Polylactic Acid (PLA), Polycarbonate (PC), Polyamide (PA), Polystyrene (PS), lignin, and rubber, among many others.

IV. RESULT

We considered 50% infill while printing; basically, infill gives us the strength of the final product. That is, by increasing the thickness and support in the printing, we can make the design more sustainable and rigid by increasing the infill up to 100%, but this might affect the cost of the final outcome.

Some specification of product:

Material	PLA
Weight of Orthosis	26 gram

Table no. 1: Product Specification

This product is very light if it is compared with the conventional method, i.e., POP cast. It is waterproof, It can also be used while bathing which is not possible with the POP cast.. So with that, particular cannot be taken while bathing in water. This 3D printed orthosis cast can also wear and remove it very easily without any difficulty, or pain. While removing and wearing the POP cast, it get hurt, so that problem is overcome by this device.

Fig.no.8: 3d printed model

V. CONCLUSION

The final product has been designed in accordance with the objectives and challenges raised. It would benefit people suffering from osteoarthritis by helping them perform basic day to day tasks. Also, people suffering from bone fractures can consider using 3D printed mold instead of POP mold, as it has high chemical resistance, is easy to apply and remove, is reusable, and does not get damaged by water, unlike POP, which makes it more convenient.

VI. FUTURE SCOPE

- Adjustable molds can be made by using velcro straps
- 3D printed Orthosis products can also be implemented to other body parts suffering with Osteoarthritis such as neck, back and knees.

VII. ACKNOWLEDGMENT

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