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Efficacy of 3D Printed Finger Prosthesis for patients affected with Hansen's Disease to Restore Hand Function

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ABSTRACT

Introduction

The greek word LEPROSY was renamed by the term Hansen's disease by Norwegian physician **Gerhard Armauer Hansen.** In 2009, WHO Goodwill Ambassador Yohei Sasakawa called for an end to usage of the word leprosy, since he described it as 'an extremely damaging term' that contributes to stigma and impacts human rights. Since 2010, leprosy mission gives assurance that the word is not condoned by media channels or used by public figures. HD ranges from mild to severe (based on one or more skin areas affected and damage caused to organs).There were 5.2 million people affected by leprosy globally, in 1980 but by 2020 this decreased to fewer than 2,00,000. Leprosy can affect people in many ways. The Cochrane database of systemic reviews , 2019 lists that 30% of people affected with leprosy experience nerve damage. People with untreated leprosy become visibly disfigured often have psychologic and social problems. Mosby's Medical Dictionary 2009 defines trophic ulcers as "a pressure ulcer caused by external trauma to a part of body or by vascular insufficiency leading to loss of afferent nerve fibres. The most severe complications result from infection of the peripheral nerves, which causes deterioration of sense of touch and inability to feel pain and temperature. The nerve damage is reversible when treated early, but becomes permanent when appropriate treatment is not available for sufferer. Damage to nerves may cause loss of muscle function, leading to paralysis. It may also lead to sensation abnormalities or numbness, which may lead to additional infections, ulcerations, and joint deformities. Also, damage to peripheral nerves may cause muscle weakness that can result in deformities. M. leprae attacks nerve endings and destroys the body's ability to feel pain and injury. Without feeling pain, people with leprosy have an increased risk of injuring themselves. In some cases, autoamputation has been reported to affect the tip of fingers. People with peripheral nerve damage may unknowingly burn, cut, or otherwise harm themselves. Infected nerves may enlarge also & this can be palpated. The fingers may be weakened, causing them to curve inward (claw hand).

When therapeutic amputation is decided for a patient affected with HD, occupational therapist can suggest preserving as much of hand as possible, to prepare wearing 3D printed prosthesis. 3-D printing is a new rising technology, Objects made in 3D printing range from plastic figurines and mould patterns to steel machine parts and titanium surgical implants. Related to Hansen Disease, It facilitates manufacturing hand parts with irregular and uncommon geometric shapes. Freedom offered by 3D

printing techniques has paved the way for the application of new design for best appearances. The advantages of 3D printing could be used to fabricate prosthetic hands based on the biological design principles.

The purpose of this study is to assess efficacy of 3-D printed finger prosthesis to manipulate objects & to restore hand function in HD clients.

Keywords: Hansen disease, auto amputation, ulceration, 3D printing technology, hand function, object manipulation.

Aim of the study

To assess Hand function, of Hansen Disease patient who have undergone auto/ therapeutic amputation due to disease pathology & find the effectiveness of fabricated 3D prosthesis in manipulating objects.

Objectives of study

To select patients undergone amputation due to Hansen's disease
To analyse the needs of patients related to Hand function with Jebsen Taylor assessment form.
To fabricate 3-D prostheses as suitable to individual patients.
To analyse its effectiveness related to manipulation of objects by hand.

Method of study

Patient with Hansen disease who have already undergone finger amputation, attending treatment at leprosy mission centre, Pallipadai were included for the study. Both Male and Female clients, having willingness to wear fabricated prosthesis were included for study. All patients were assessed on hand function using Jebsen Taylor hand function scale before and after providing 3D prosthesis. Scores noted were plotted for comparison on efficacy of the 3D Prosthesis.

Results

A total number of 10 Hansen disease patients were included in the study. All patients were assessed on hand function using Jebsen Taylor hand function scale before providing 3D prosthesis. After wearing such prosthesis, the timing variations in grasp & pinch demonstrates, effectiveness of the 3D prostheses.

Conclusion

By the study, it can be concluded that 3-D printed prosthesis is efficient on restoring hand function for Hansen disease patients.

Introduction

Hansen’s disease is caused by slow-growing bacteria called Mycobacterium leprae. Hansen disease (leprosy) affects nerves, skin, eyes, and nasal mucosa. With early diagnosis and treatment, the disease can be cured. People with Hansen’s disease can continue to work and lead an active life during and after treatment. However, if left untreated, the nerve damage can result in crippling of hands and feet, paralysis, and blindness. Literature review says that average incubation period is five years. Bone loss occurs in anesthetic, paralyzed fingers or toes and is a late, advanced consequence of infection and injury to the peripheral nerves proximal to the wound or ulcer.The extremities are prone for Auto

amputation also, common phenomenon seen at the fingers or toes. Surgical amputation is indicated when a part is gangrenous or when the severely deformed anaesthetic part ulcerates frequently.

The fingers and toes "drop off" ,Trauma to anesthetic limbs in any type of leprosy may result in ulceration and, without diligent care of early injuries, secondary infections may culminate in secondary osteomyelitis due to common Gram-positive or -negative organisms. This absorption can be extensive, even resulting in the absorption of all digits from an extremity. Hence ICD allotted code A 30 to this condition.

Patients affected with leprosy may also have genes that make them susceptible to the infection once they are exposed.Family members living in the same home with the person affected are suggested to avoid contact with airborne droplets from nose or mouth, to take a skin biopsy & BCG booster earlier which may improve their immunity.

The term 3D printing originally designated a specific process patented as 3DP by scientists at the Massachusetts Institute of Technology (MIT) in 1993. This printing, fabricate three-dimensional objects, by layering two-dimensional cross sections sequentially, one on top of another. This process is similar to fusing of ink or toner onto paper in a printer. The layering is repeated hundreds or thousands of times until the entire object has been finished throughout its vertical dimension. Central to all of them is computer-aided design, or CAD. 3D printing techniques has paved the way for the application of new design approaches; for example the non-assembly design approach. Current 3D-printed hands are based on a mechanical-inspired design. The advantages of 3D printing could be used to fabricate, prosthetic hands based on the biological design principles in human hands. In this study, we therefore aimed 3D-printed hand prostheses that are quite different in appearance and features from traditional ones. When manufactured by 3D printing, quite complex geometries can be created. So these prostheses usually have strength and are, in general, better-designed products.

INJURIES AND AMPUTATIONS in HD

- A sharp cut
- A crushing injury
- A tearing force may cause

Partial amputation — some structures remain attached or

Complete amputation— the entire fingertip is removed.

An injury can damage any part of the fingertip, including:

- Skin and soft tissue
- Fingertip bone (distal phalanx)
- Nail and underlying nailbed

The tips of longer fingers tend to be injured more often because they are rich with nerves and are extremely sensitive. It may even result in permanent deformity or disability.

ADVANTAGE OF 3D PRINTER MAKING PROSTHESES

There are several advantages over traditional fabrication

- Low cost
- Very light weight

- Flexible printing
- Sustainable
- Faster
- Custom design
- Cosmetic & functional restoration
- Fashionable
- Environment-friendly

Bioprinting is based largely on existing printing technologies, such as ink-jet or laser printing, but makes use of "bioink"

JEBSEN TAYLOR HAND FUNCTION TEST

The **Jebsen-Taylor Hand Function Test** is a standardized and objective measure of hand function assessment using simulated activities of daily living . Easy applicability in clinical settings within a short time by using readily available materials, is the advantage of the test. Moreover, objective scores for pre & post therapy comparison is available. It has 7 items and takes approximately 15-45 minutes to administer. The 7 items include: writing, turning over 3-by-5 inch cards, picking up small common objects, simulated feeding, stacking checkers, picking up large light objects and picking up large heavy objects. The results are measured by timing taken to accomplish each task. The tests are always presented in the same order and are performed with the non-dominant hand first.

REVIEW OF LITERATURE

- Cameron Kia et al (2022) done a study on Spinal Implant Osseo integration and the Role of 3D Printing: The use of interbody implants for spinal fusion has been steadily increasing to avoid the risks of complications and donor-site morbidity when using autologous bone. Understanding the pros and cons of various implant designs can assist the surgeon in choosing the ideal interbody for each individual patient. This article, discusses the biology of osseointegration, the use of surface-coated implants, as well as the potential benefits of using 3D-printed interbodies.
- Hadi Moeinnia et al (2022) done a study Novel Grasping Mechanisms of 3D-Printed Prosthetic Hands Herein, the current challenges and approaches for enhancing the grasping function of 3D-printed hand prostheses. Three technology sectors are discussed for the efficient grasping motion of hand prosthetics: 1) how to recognize the user's desired grasping gestures by sensing systems; 2) how to power the prosthesis for grasping objects through different actuation systems; and 3) how to perform the grasping motion by 3D design and mechanisms. This article reviews valuable information regarding the current innovations toward improving prosthetic hands' grasping function to help researchers design more functional hand prostheses.
- Christopher Crick et al (2021) done a study on Self-trainable 3D-printed prosthetic hands. 3D printed prosthetics have narrowed the gap between the dollars cost of traditional prosthetic designs and amputees' needs. However, the World Health Organization estimates that only 5-15% of people can receive adequate prosthesis services. To resolve the lack of prosthesis supply and reduce cost issues (for both materials and maintenance), this paper provides an overview of a self trainable user-customized system architecture. This result demonstrates that applying user-customized training to a prosthetic hand can satisfy individual user requirements in real-life activities with high performance.

- Carlo Mangano et al (2020) done a study on Custom-made 3D printed subperiosteal titanium implants for the prosthetic restoration of the atrophic posterior mandible of elderly patients, although this study has limits (small patient sample and short follow-up), DMLS has proven to be an effective method for fabricating accurate subperiosteal implants, with high survival rates. This may represent an alternative treatment procedure in elderly patients with a severely atrophic posterior mandible, since it allows avoidance of regenerative bone therapies.
- Juan Sebastian Cuellar et al (2020) done a study on Design of a 3D-printed hand prosthesis featuring articulated bio-inspired fingers. Various upper-limb prostheses have been designed for 3D printing but only a few of them are based on bio-inspired design principles and many anatomical details are not typically incorporated even though 3D printing offers advantages that facilitate the application of such design like adaptive grasping, articulated fingers and minimized post-printing assembly.
- Abbady et al. (2019) did a study on 3D-printed prostheses in developing countries: a systematic review of Low material costs, aesthetic appearance, and the possibility of personalized fitting make 3D-printed prostheses a potential solution for patients with limb amputations. However, the lack of (homogeneous) data shows the need for more published research to enable a broader availability of knowledge about 3D-printed prostheses.
- Immaculada Llop-Harillo et al (2017) did a study on a System for the experimental evaluation of anthropomorphic hands. Application to a new 3D-printed prosthetic hand prototype, a new actuation device and protocol for testing the grasping performance of low-cost 3D-printed hand prototypes. The actuation device is connected to the forearm of a healthy user and allows him to use his thumb and fingers to control any prototype moved by up to six tendons attached to this device. This study also presents a new design for a low-cost 3D-printed prosthetic hand, called the IMMA hand. Index and ring finger motions are highly correlated in over half of the grasp actions performed for both subjects.
- Yahya E. Choonara et al (2016) did a study on 3D printing and the effect on medical costs: 3D printing (3DP) is the art and science of printing in a new dimension using 3D printers to transform 3D computer-aided designs (CAD) into life-changing products. In addition, the loss of skilled labor in producing medical devices such as prosthetics and other devices may affect developing economies. This review objectively explores the potential growth and impact of 3D costs in the medical industry.

Methodology

Aim of the study

To assess Hand function, of Hansen Disease patient who have undergone auto or therapeutic amputation due to disease pathology & find the effectiveness of fabricated 3D prosthesis in manipulating objects.

Objectives of study

To select patients undergone AMPUTATION due to Hansen's disease

To assess the needs of patients related to Hand function with Jebson Taylor (standardized assessment form).

To fabricate 3-D prostheses as suitable to individual patients.

To analyse its effectiveness related to manipulation of objects by hand.

STUDY DESIGN
Single group of Experimental study

ASSESSMENT TOOL
Jebson Taylor Hand Function assessment form.

Jebsen Hand Function Test Worksheet
(for scoring HF with prostheses & without prostheses)

Patient Name: Date of assessment:

The tests are performed with the non-dominant hand first.

The results are measured by timing the time taken to accomplish each task.
1. Writing:__seconds
2. Card turning:_____seconds
3. Small common object:_____seconds
4. Simulated feeding:_____seconds
5. Checkers:_____seconds
6. Large light object:_____seconds
7. Large heavy object:_____seconds

Time taken for each task(totally seven) is noted for comparison of speed & efficiency in hand function wearing 3D prosthesis.

STUDY SETTING
Patient visiting is done through direct contact programme, using their registration details given at Leprosy mission centre, Chidambaram.

INCLUSION CRITERIA
➢ Patient with Hansen disease undergone finger amputation
➢ Both Male and Female clients
➢ Having willingness to wear fabricated prosthesis

EXCLUSION CRITERIA
➢ Other than Hansen Disease, Traumatic conditions Road traffic accidents, Nerve injuries (PNI) patients are excluded.

PROCEDURE
Hansen Disease patients who have undergone partial or full finger amputation were selected. They were assessed using the Jebsen Taylor Hand Function Test before applying suitable prostheses to know the deficits in Hand function without prosthesis. The 3D Prostheses fabrication was done at the centre,

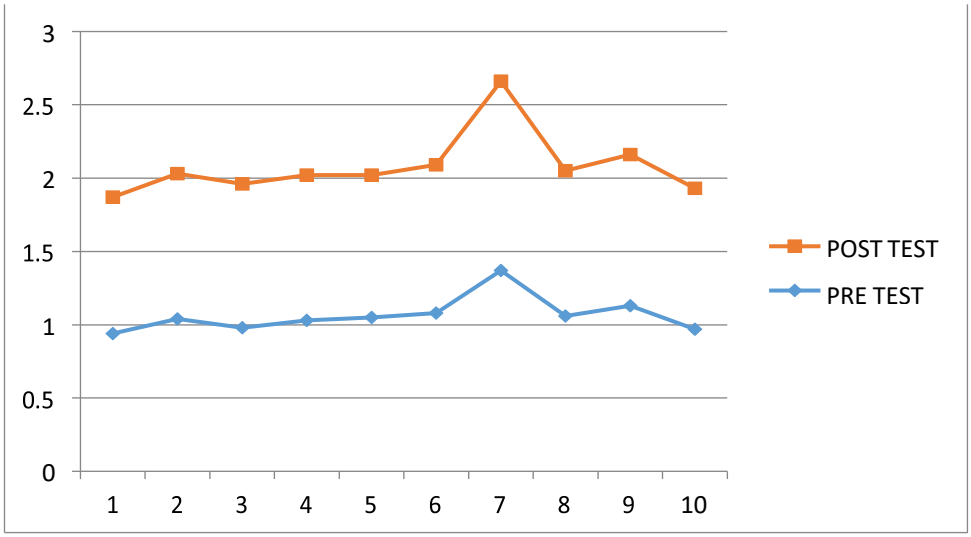
provided to them after finding their willingness to use them. They were trained to use PROSTHESES in various types of grasp functions. Again they were assessed as post therapy measurement of Hand Function. Comparison of the timing taken for each task performance before and after 3D customized finger prosthesis wearing was done. It was noted in above mentioned worksheet. Results framed based on this.

DATA ANALYSIS

DOMINANT HAND (Jebsen Taylor HF)

PLOT DIAGRAM for **PRE-TEST AND POST-TEST Values**

(Dominant hand)

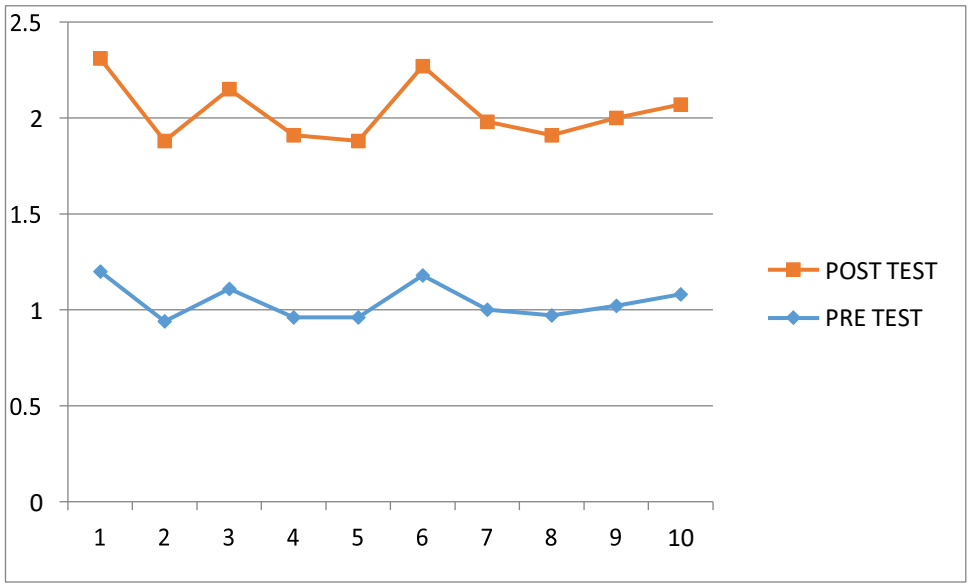


PARAMETERS	PRE-TEST	POST-TEST
N	10	10
MEAN	1.065	1.016
S.D	0.11	0.09

In pre and post test assessment, pre test (1.065±0.11) score is having higher mean value than post test (0.016±0.09). Hence, there is significant difference between OBJECT MANIPULATION AT DOMINANT HAND with prosthesis usage.

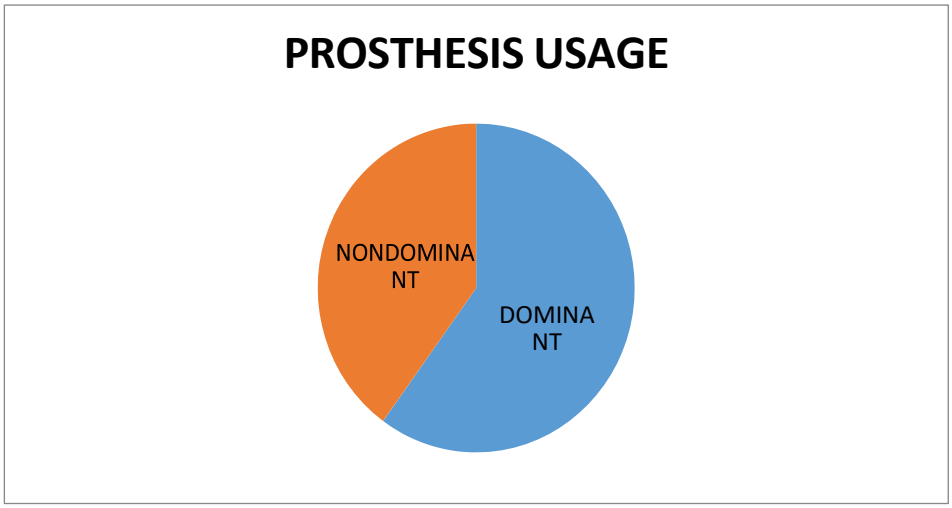
NON-DOMINANT HAND (Jebsen Taylor HF)

PLOT DIAGRAM for PRE-TEST AND POST-TEST Values



PARAMETERS	PRE- TEST	POST-TEST
N	10	10
MEAN	1.042	0.994
S.D	0.090	0.062

Among the patients participated in the study, dominant (right hand) prosthesis was used by six patients, non dominant (left hand) prosthesis used by four patients.



RESULTS

A total number of 10 Hansen disease patients were included in the study. All patients were assessed on hand function using Jebsen Taylor hand function scale before providing 3D prosthesis. Among them, right hand (dominant) prostheses were used by six patients, non-dominant (left hand) prostheses used by four patients. In pre and post test assessment compared, pretest (1.065±0.11) score is having higher mean value than post test (0.016±0.09). After 3D prosthesis wearing, there is the significant difference

between object manipulation at dominant hand with prosthesis usage is observed. Timing variations in grasp & pinch demonstrates effectiveness of the 3D prostheses.

DISCUSSION

The purpose of the study was to restore hand function by providing 3D finger prosthesis. Ten appropriate patients were included as samples. Based on inclusion criteria the patients were selected, assessed with jebsen taylor HF test. After obtaining proper consent, work on fabrication of prostheses at the leprosy mission centre carried out. Wearing this artificial hand, Scores of jebsen taylor hand function test was made again. It was used to find the efficacy of 3D prosthesis. As expected there was no difference between male & female time consumption in the HF test. With the 3D prostheses, females were finding easy to do household activities.

LIMITATION of the study

- This study was conducted with TEN (HD) patients who were willing to use 3D prostheses. More number of patients could be assessed in future.
- Durability of the prostheses in different occupations differs.

RECOMMENDATION

- Study can be conducted at various age groups, with different occupations of clients.
- At different occupations, efficacy of prosthesis could be evaluated.

CONCLUSION

By the study, it can be concluded that 3-D printed prosthesis is efficient on restoring hand function for Hansen disease patients.

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