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RESEARCH ARTICLE

Evaluating the clinical benefit and acceptance of a bespoke 3D-printed splint for the treatment of mallet finger injury: A pilot study in a cohort of patients

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Abstract

Mallet finger injuries due to forced flexion of the distal interphalangeal joint represent a common reason for hospitalization. These injuries are primarily managed using generic Stack splints. The gold standard of care is custom splinting by a specialized hand therapist. However, this is not widely available due to staffing constraints. The aims of this study are to: (i) evaluate whether treating mallet finger injuries with a custom three-dimensional (3D)-printed splint is clinically beneficial, and (ii) assess patient and healthcare professional (HCP) acceptance and experience of bespoke 3D-printed mallet splints over generic splints. Ten adult patients with closed mallet finger injury were recruited in this study, which was conducted across three Injury Units in the University of Limerick Hospital Group (ULHG). Each patient's injured finger was measured using calipers and subsequently fitted with a bespoke 3D-printed splint. Clinical benefit and acceptance of bespoke 3D-printed splints for the treatment of mallet finger injury was assessed. The results indicate that it is clinically advantageous to use a custom 3D-printed splint over a premolded generic splint. Out of the ten patients recruited, eight had successful outcomes based on the occupational therapist (OT) measurements using the Crawford classification scale. The results showed that 40% of patients scored excellent, 30% good, 30% fair, and 0% poor. In addition, in terms of patient and HCP acceptance of the splint, nine of the ten patients stated that they would use the 3D-printed custom splint again, if needed, in the future. In conclusion, a high level of patient and HCP acceptance signifies the clinical advantage of using 3D-printed splints. This pilot study shows that advances in 3D printing could make custom splinting a viable option for use in personalized healthcare.

Keywords: Mallet finger; Mallet Injury; 3D printing; Additive Manufacturing

1. Introduction

An epidemiologic study of soft tissue musculoskeletal injuries found that mallet fingers were the fifth most common bodily injury.¹ Thus, mallet finger injuries are common in Emergency Departments (ED) and Injury Units (IUs) of hospitals.² Mallet finger injuries result from forced flexion or hyperextension of the distal interphalangeal joint (DIPj). The overextension of the DIPj tears the extensor tendon where it inserts into the distal phalanx. This injury may occur with or without an associated fracture, resulting in the loss of extensor mechanism. If not managed appropriately, a permanent extension lag and a possible swan neck deformity may occur.³ These injuries commonly occur across all demographic groups as a result of work or sports activities.⁴ Another less common presentation is spontaneous mallet injury, whereby no external trauma has occurred to cause the injury. This form of injury, though less common, is associated with other underlying illnesses, such as rheumatoid arthritis or osteoarthritis.⁵

Mallet finger injuries should be treated with immobilization or “static” splinting in extension or slight hyperextension for up to 8 weeks, which includes 2 weeks of night splinting at the end of treatment. This mode of treatment, when supported by effective discharge advice and strong patient compliance, allows healing by maintaining an upward force on the injured finger until the tendon injury or fracture heals.⁶ The splint must be worn continuously, and the proximal interphalangeal joint (PIPj) must have enough clearance to bend to ensure the patient does not lose range of movement. If the splint is removed and the injured finger is allowed to bend, the extensor tendon may re-rupture, requiring the splinting process to be repeated. This can delay healing by several weeks and can lead to a swan neck deformity.⁷ An unhealed mallet finger injury may not function properly, resulting in pain and, in time, arthritis.⁸

There are several splinting options that follow similar modes of treatment. Some splints are provided by companies directly to hospitals, an example being prefabricated generic Stack splints. Other splints are custom-made for patients, with the most notable example being the thermoplastic splint, which is molded, typically by a skilled hand therapist, to fit the patient’s finger. Of these splinting methods, custom splinting is the preferred treatment option.^{9,10} However, prefabricated generic Stack splints remain the most common treatment provided by healthcare facilities.¹¹ A study that investigated the conservative management of mallet splinting in Irish

hospitals found that ED teams are restricted in their choice of splint due to stock availability.¹² Being readily available in the ED, generic Stack splints appear to be the most used in that department.

Generic Stack splints are not without limitations. Due to variability in finger size and shape between patients, and swelling of the injured finger, a correct or optimal fit may not be achieved. This can then affect patient compliance.¹³ Stack splints typically come in eight sizes, but perfect fit may not be realized for every patient. In addition, generic Stack splints do not consider the finger length of the individual patient, so the PIPj may not be free to move if the splint is too long. There is no proven benefit to recovery when both the PIPj and DIPj are immobilized. Therefore, patients need to be able to continue to move their PIPj while the DIPj is immobilized.¹⁴ The generic Stack splint also needs to be secured in place. This typically involves taping around the injured finger. However, this can be challenging for patients who are trying to manage the injury by themselves. In addition, generic Stack splints have been found to increase the risk of skin complications compared to custom-made orthoses. Skin complications such as mechanical dermatitis from tape placement and adhesive sensitivity have been documented for many years.¹⁵

The numerous challenges faced by hospital staffing systems make provision of personalized healthcare difficult. Custom-made splints require a specialized hand therapist to provide individualized care. Hand therapists apply the required splint to the patients, based on their anatomy. They also factor in their daily activities to help optimize recovery. These custom splints take approximately 30 min to create. Unfortunately, the low availability of specialist hand therapists in Irish hospitals indicates that custom splinting for mallet injuries is generally not available.¹²

Three-dimensional (3D) printing offers tremendous opportunities in the development of patient-centered bespoke care. The use of 3D printing to create bespoke devices to directly treat patients has been increasing in recent years.¹⁶ Advances in materials, printing technology, and experience have led to increased clinical use, moving away from the one-size-fits-all model. 3D printing is now beginning to harness medical imaging data to optimize patient-specific devices such as splints and casts. Initially, 3D printing was used primarily for anatomical modeling, to aid in education and planning.¹⁷ However, its application has been expanded to the creation of patient-specific devices in the realm of point of care (POC). 3D printing can enable the production of anatomically

matched and patient-specific devices with high tunability, and can provide an innovative approach to individualized healthcare, thus expanding the manufacturing of custom devices within the healthcare settings.¹⁸

Previous studies have assessed the feasibility of treating mallet fingers with 3D printing technology. Among these studies, five tested 3D-printed devices on non-injured volunteers.¹⁹⁻²³ Wong et al. assessed the feasibility of 3D printing a customized mallet splint on site for 13 non-injured Mars Desert Research Station mission crew members.¹⁸ Choi et al. compared custom casts comprising plaster of Paris, evaluated their use against a 3D-printed splint, and conducted a wearability assessment in an unreported number of non-injured participants.¹⁹ Zolfagharian et al. designed and 3D-printed a custom mallet splint for one healthy volunteer.²⁰ Papavasiliou et al. compared custom 3D-printed splints to conventional custom-made thermoplastic splints and assessed patient comfort and satisfaction for hand injuries.²¹ Gupta et al. assessed a 3D-printed mallet splint on 20 non-injured volunteers.²⁴ Nam et al. aimed to treat an injured patient with a mallet injury using a 3D-printed device.²³ These six studies did not assess bespoke 3D-printed mallet splints in the treatment of mallet injury for multiple patients. Also, none assessed patient and healthcare professional (HCP) acceptance of the 3D-printed mallet splint.

The primary aim of this study is to evaluate the clinical benefit of applying a custom 3D-printed mallet splint to multiple patients requiring splinting for mallet injury. The secondary aim is to explore patient and HCP acceptance of 3D-printed mallet splints, in relation to fit, comfort, and appropriateness. The customization of the 3D-printed splint, where the anthropometrics of each patient guided the design, was key to providing comfort while providing clinical benefit. This is the first prospective, multi-site study offering custom 3D-printed devices to a cohort of patients ($n = 10$) for treating mallet finger injury.

2. Materials and methods

This study was approved by the Research Ethics Committee of ULHG (reference 087/2022). Written informed consent was obtained from all participants before beginning the study.

2.1. Materials

The bespoke splints were printed on a Figure 4 (3D printer make) standalone 3D Printer (3D Systems, South Carolina, United States of America) using the PRO-BLK material from the same manufacturer.

2.2. Study design

This was a multi-site study conducted in three hospitals across ULHG. This hospital group saw approximately

71,315 attendances at their ED and IUs in 2019.²⁵ To that end, the inclusion of three units provided a representative group for study recruitment. The time frame for recruitment for the study was 6 months, commencing in January 2023 and ending in June 2023.

The inclusion criteria were adult patients presenting to the ED or IU with a Type 1 or Type 2 closed mallet finger injury based on the Doyle Classification System.²⁶ The exclusion criteria were injuries with obvious abnormal anatomy or skin complications. There was no randomization of participants. All patients that met the inclusion criteria were invited to participate in the study by their treating HCP.

2.3. Design and production of 3D-printed splints

Measurements at eight discrete points of the injured finger were recorded (Figure 1) using a vernier calipers (Mitutoyo brand) with a resolution of 0.01 mm.

Calipers were the chosen measuring device because they were available to the research team at the beginning of the study. They were also more practical because they did not require specialist equipment (3D scanner, dedicated computer) or specialist training on a new technology.

A 3D CAD model of the custom splint was designed in SolidWorks® (Dassault Systems, France) using the dimensions recorded from the patient. A design table was used to automatically modify a standard base model using the unique dimensions of the patient, creating a bespoke splint for every patient with no additional design effort or engineering required (Figure 2).

2.4. Study process

2.4.1. Initial presentation

At their initial presentation ($t = 0$ days), patients who met the inclusion criteria and consented to participate in the study were allocated four follow-up appointments ($t = 7$, $t = 9$, $t = 21$, and $t = 56$ days; Table 1).

The patients were fitted with a generic Stack splint at their initial presentation and were instructed to wear this temporarily until the 3D-printed splint was ready approximately 7 days later. This was to ensure immediate commencement of a treatment and to allow for any swelling to reduce before being measured and fitted for the 3D-printed splint. The Stack splint was, therefore, worn during the period when the patient's finger was most swollen. The logistics of the study did not allow deviation from this.

Each patient was given discharge advice consistent with the normal standard of care in each unit. The discharge

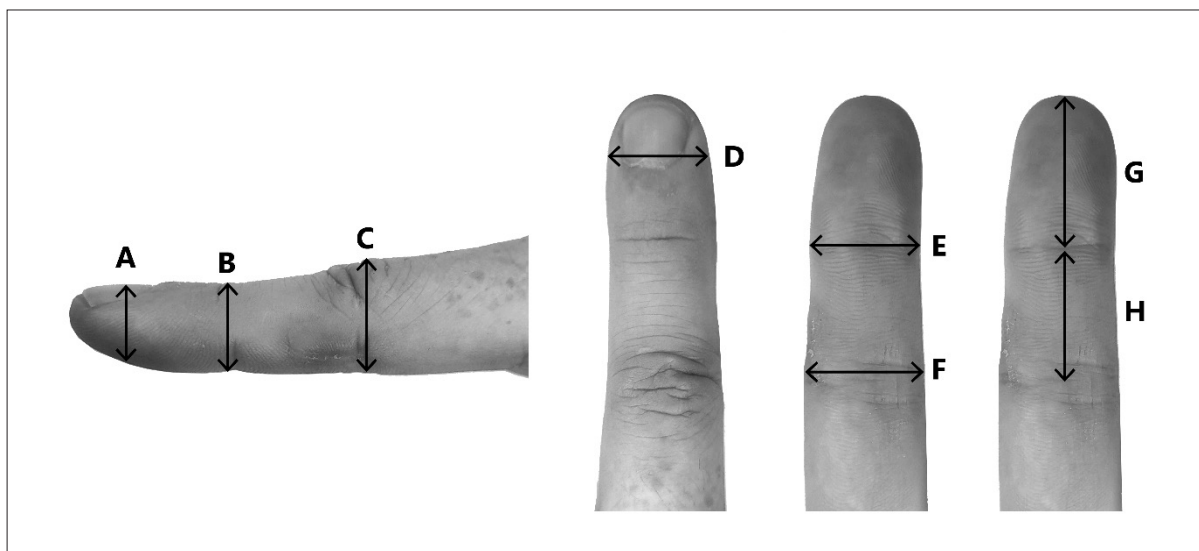


Figure 1. Points of measurement for injured finger. Original picture based on Wong.¹⁸

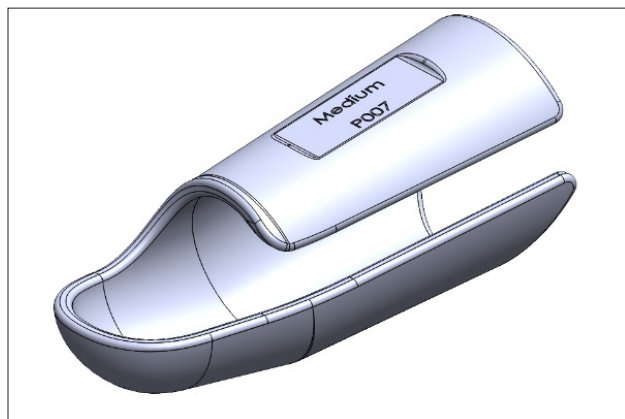


Figure 2. Image of custom 3D-printed splint.

advice was the same for the Stack splint and the 3D-printed splint.

2.4.2. Measuring (t = 7 days)

Each measuring appointment was conducted with a single member of the research team (A.O.'S) to control for inter-individual differences in measurement skills or approaches.

An HCP (nurse, advanced nurse practitioner, or doctor) was also present to ensure the finger was kept straight to avoid re-injury.

2.4.3. Fitting (t = 9 days)

A 3D-printed splint was manufactured using the measurements of the patient's finger. The splint was delivered and fitted to the patient in the hospital. An HCP oversaw the fitting to evaluate the injured finger for skin integrity or other complications that could preclude the patient from further participation in the study.

2.4.4. Mid-trial review (t = 21 days)

A consultant in emergency medicine reviewed each patient after wearing the 3D-printed splint for 21 days to evaluate skin integrity and general progress. If any concerns were noted regarding compliance or comfort, the patient was changed to an alternative treatment method and removed from the study.

2.4.5. Final review (t = 56 days)

A final review appointment including an interview was conducted at 56 days by an OT with expertise in the

Table 1. Patient appointments and study stages

Initial presentation (day 0)	Measuring (day 7)	Fitting (day 9)	Midtrial review (day 21)	Final review (day 56)
Patient presented to hospital. Standard treatment commenced	Finger measured	3D-printed splint fitted	Review by consultant in emergency medicine (skin, pain, progress)	Final interviews with researcher and OT

provision of hand therapy assessments and intervention (M.S.). The lead researcher (U.C.) was also present.

2.5. Patient interview

Initially, the patient was interviewed regarding their perception and acceptance of the 3D-printed splint using a modified form of the Quebec User Evaluation of Satisfaction with assistive Technology QUEST (Version 2.0).²⁷ The questionnaires were validated by an external group of experts before commencing the study (a consultant in emergency medicine, an advanced nurse practitioner, a research nurse, and an OT).

The patient's satisfaction with the Stack splint and the 3D-printed splint was assessed using a Likert scale and free-text answers. It was explained to each patient that the initial splint was applied when the finger was likely to be most swollen. Patients were encouraged to be cognizant of this when answering the questionnaire to avoid bias against their initial splint.

The second part of the interview was conducted by the OT with a focus on clinical outcomes and acceptance.

2.6. Measurements

The OT removed the splint and assessed the range of movement of the DIPj using a Rolyon® finger goniometer (Smith and Nephew, London, UK). The patient's measurement was compared to the Crawford classification scale. This is the most commonly used outcome classification tool for mallet finger treatment.²⁸

- Excellent: No pain with full range of motion at the DIPj
- Good: Less than 10-degree extension deficit
- Fair: 10–25 degrees of extension deficit with no pain
- Poor: More than 25 degrees of extension deficit or persistent pain

If there was an extension deficit of more than 10 degrees or poor active extension, the splint was continued for a further 2 weeks, followed by night splinting for a further 2 weeks, as directed by the OT.

2.7. Acceptance

Patient feedback was collected in the free-form section of each questionnaire to capture each patient's detailed experience of both splints. Both the patient and the OT were asked if they would use the 3D-printed splint again.

2.8. Data analysis

Data from the questionnaires were tabulated and analyzed using Microsoft Office Excel, and descriptive statistics were used to describe the data.

3. Results

3.1. Participation and study completion rate

Over a 6-month period, 16 patients were recruited, with 10 completing the study. There were eight males and two females, and their average age was 58. All patients sustained their injury through trauma. Two patients withdrew from the study due to an inability to attend all scheduled appointments as required. One patient failed to attend any follow-up appointments after the bespoke splint was fitted, despite attempts to contact the patient and rearrange appointments.

The intention was that all patients would wear a generic Stack splint before being fitted with the 3D-printed splint. However, one patient could not tolerate the generic Stack splint because a close fit could not be obtained. In that case, a dorsal aluminum splint was applied. This patient's data are not included in the results.

On mid-trial review with the consultant in emergency medicine, two patients were found to have osteoarthritic changes to their finger joints. After review by the OT and consultant in emergency medicine, it was decided that these were more complicated injuries. Consequently, these patients were removed from the study and prescribed custom thermoplastic splinting and regular reviews by the OT. The ten patients who completed the study wearing the 3D-printed splint attended the final interview with the lead researcher and OT.

3.2. Clinical outcome

Out of the ten patients recruited, eight had successful outcomes based on the OT measurements while using the Crawford classification scale. The results showed that 40% of the patients scored excellent, 30% good, 30% fair, and 0% poor.

Of the two patients with unsuccessful outcomes, one abandoned the use of the splint within the first 6 weeks and returned to participation in sporting activities; the other repeatedly bent the injured finger during hand washing due to a misunderstanding of discharge advice.

3.3. Clinician acceptance

The OT was asked the following question: "Based on your experience with this patient, would you consider a 3D-printed splint such as this to be potentially suitable for other patients with closed hand injuries?"

In all ten cases, the OT indicated they would be happy to use a 3D-printed splint in future in place of Stack splints. However, they noted the need to improve aeration and durability to ensure the effectiveness of the splint.

3.4. Patient acceptance

Analysis of the questionnaires revealed a clear patient acceptance of the 3D-printed splint (Table 2). All but one

Table 2. Percentage satisfaction of Stack vs. 3D-printed splint qualities

	% Not satisfied at all		% Not very satisfied		% More or less satisfied		% Quite satisfied		% Very satisfied	
	Stack	3D-printed	Stack	3D-printed	Stack	3D-printed	Stack	3D-printed	Stack	3D-printed
Dimensions	0	0	20	0	50	10	20	40	10	50
Weight	0	0	10	0	40	0	40	50	10	50
Ease in adjusting	0	0	40	0	20	10	20	40	20	50
Safe and secure	0	10	30	10	40	20	20	10	10	60
Durability	10	0	10	0	10	10	20	60	50	30
Easy to use	10	0	20	0	40	10	20	40	10	50
Comfort	10	0	20	0	20	0	20	40	30	60
Effective	0	0	10	10	60	10	20	10	10	70
Easy to remove for hand washing	10	0	10	0	30	10	30	20	20	70
Easy to reapply after hand washing	10	0	0	0	50	0	30	30	10	70

patient said they would choose the 3D-printed splint again if they had reason to use it (90%).

- (i) In relation to dimensions, 50% of patients rated the 3D-printed splint as being very satisfactory compared to 10% for the Stack splint.
- (ii) In relation to the weight of the splint, 50% of patients rated the 3D-printed splint as very satisfactory compared to 10% for the Stack splint.
- (iii) In relation to ease in adjusting, 50% of patients rated the 3D-printed splint as being very satisfactory compared to 20% for the Stack splint.
- (iv) In relation to how safe and secure the splint felt, 60% of patients rated the 3D-printed splint as very satisfactory compared to 10% for the Stack splint.
- (v) In relation to durability, 30% of patients rated the 3D-printed splint as very satisfactory in comparison to 50% for the Stack splint.
- (vi) In relation to ease of use, 50% of patients rated the 3D-printed splint as very satisfactory compared to 10% for the Stack splint.
- (vii) In relation to comfort, 60% of patients rated the 3D-printed splint as very satisfactory compared to 30% for the Stack splint.
- (viii) In relation to effectiveness, 70% of patients rated the 3D-printed splint as very satisfactory compared to 10% for the Stack splint.

- (ix) In relation to ease of removing for hand washing, 70% of patients rated the 3D-printed splint as very satisfactory compared to 20% for the Stack splint.
- (x) In relation to ease of reapplying after hand washing, 70% of patients rated the 3D-printed splint as very satisfactory compared to 10% for the Stack splint.

3.5. Patient feedback

Most patients commented on how much lighter the 3D-printed splint was. They also commented that the 3D-printed splint was at times more difficult to remove for hand hygiene because it had a tighter fit than the generic Stack splint (Figures 3 and 4). This was contrary to the original belief that the Stack splint would be tighter because it was applied for the first 7 days post injury when the finger would most likely be swollen. Patients cited this tightness as a positive during the questionnaire. They felt the splint was more comfortable because it fit neatly. Patients commented that they felt immediate relief when the 3D-printed splint was applied after the generic Stack splint.

Patients reported their injured finger swelling and decreasing at times throughout the study. Some patients developed skin complications when wearing the generic Stack splint. The lack of a custom fit caused the splint to rub against the skin, leading to blisters and discomfort. Figure 5A shows an example of an ill-fitting generic Stack splint, and Figure 5B shows skin maceration secondary to an ill-fitting generic Stack splint.

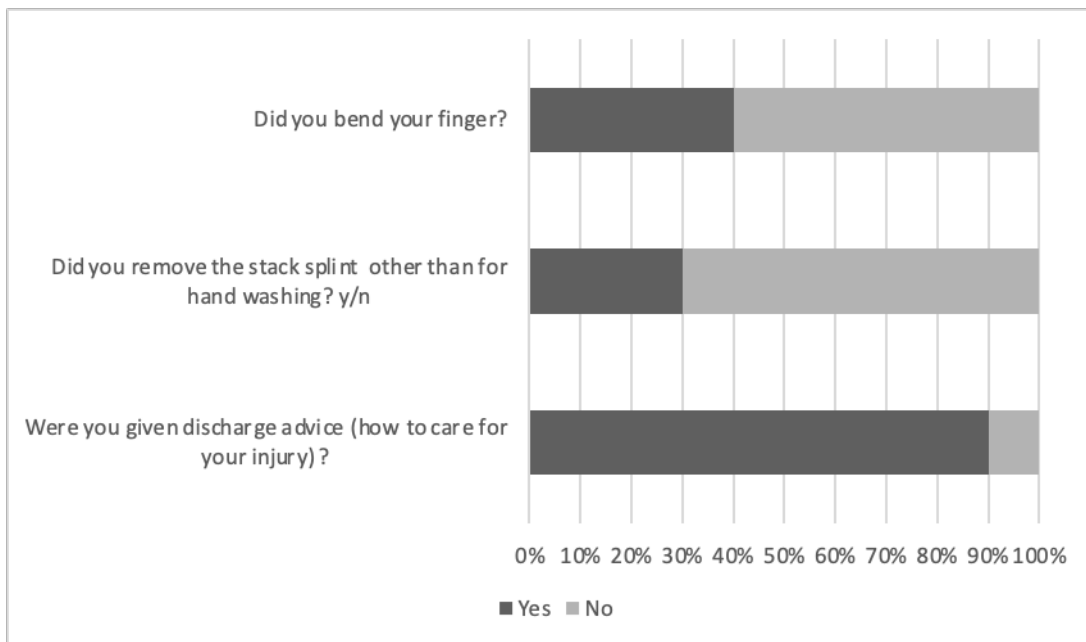


Figure 3. Stack splint foundational questions.

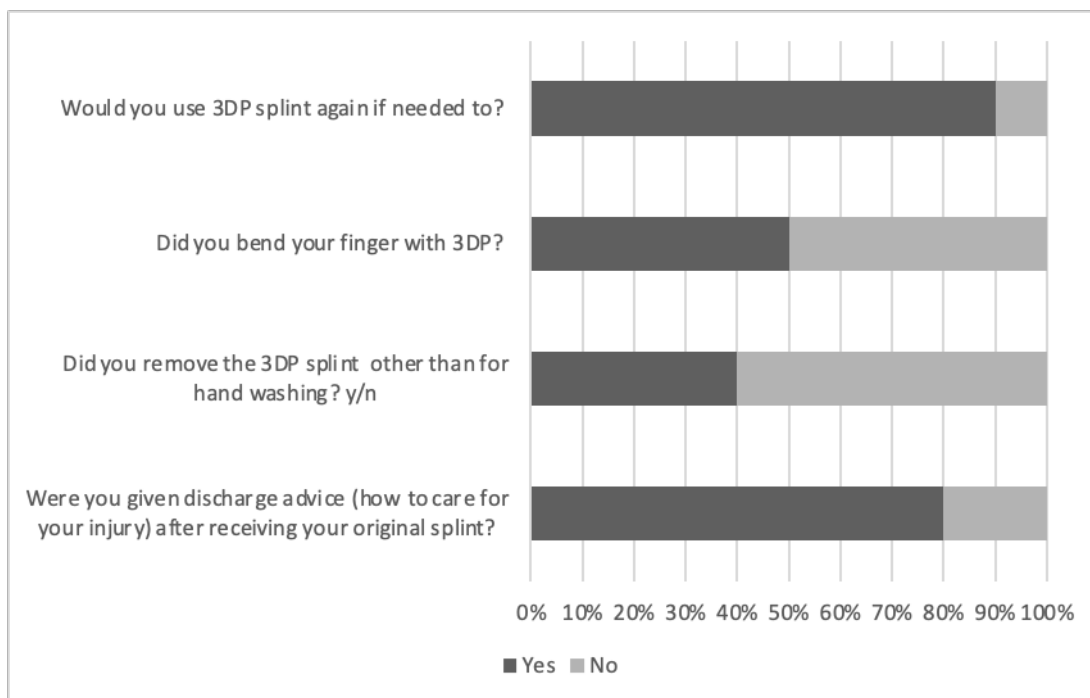


Figure 4. 3D-printed splint foundational questions. Abbreviation: 3DP, 3D-printed.

Patients were asked if they were given discharge advice (how to care for your injury) after receiving their original splint; 90% of them answered yes. Patients were then asked if they bent their finger at any point throughout their treatment; 40% of patients reported

that they did not bend their finger at any time throughout their treatment.

Nine of the ten patients reported that the 3D-printed splint began to warp and lose its structure from week 4

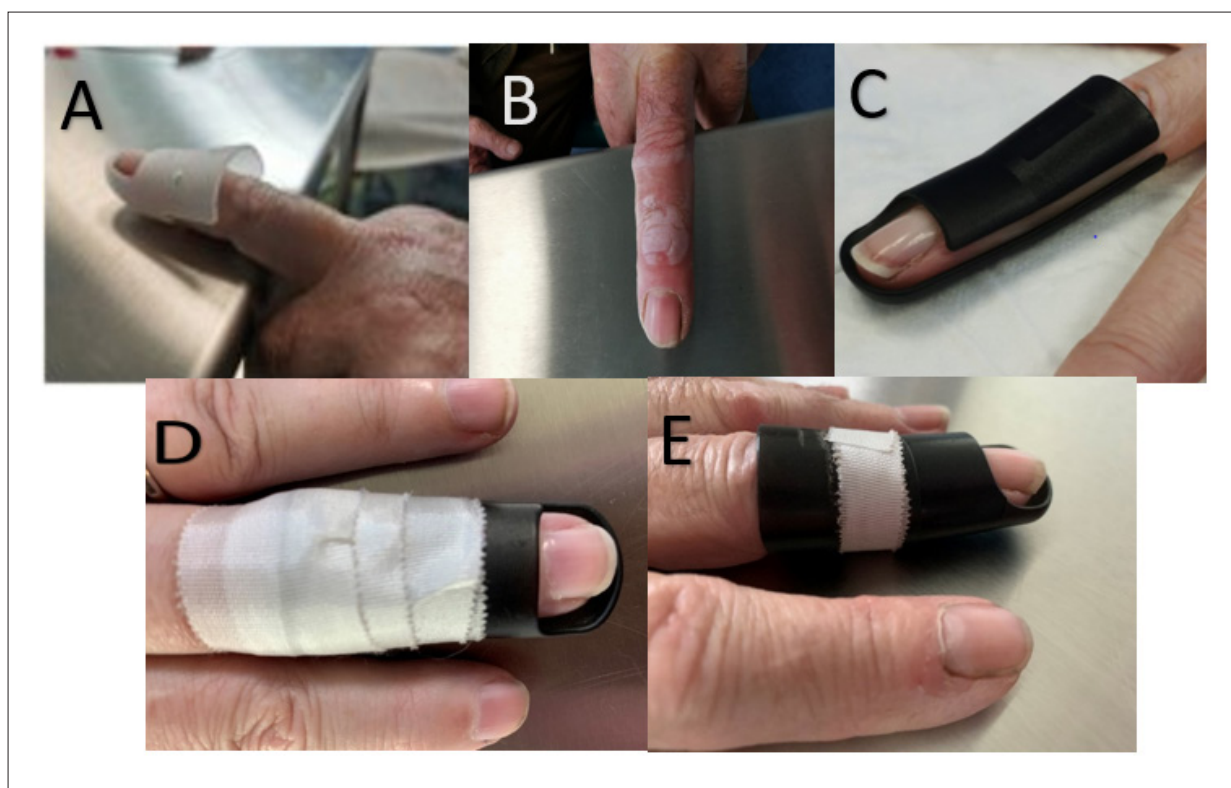


Figure 5. Selected patient photos showing generic versus 3D-printed custom splint. (A) Ill-fitting Stack splint; (B) skin maceration from ill-fitting Stack splint; (C) air-vent opening displayed along the side of the 3D-printed splint; (D) over-taping, which causes blocking of the airflow in a 3D-printed splint; (E) light taping, which secures the splint and allows airflow in the 3D-printed splint.

onward. This is an important finding because this decline in the mechanical properties of a 3D-printed material has been reported previously and needs to be addressed in future research.²⁹ This may explain why the Stack splint was rated higher than the 3D-printed splint in relation to durability (30% of patients rated the 3D splint as very satisfactory in comparison to 50% for the Stack splint for durability).

Patients also reported that the 3D-printed splint was at times warm and commented that better air flow could increase comfort. This is again an important finding as improving airflow, thus comfort, will be a key focus on the next iteration. On analyzing how patients were taping the 3D-printed splint, those who mentioned the splint was too hot at times and required improved air flow had over-taped the splint. Figure 5C shows the air vent along the side of the 3D-printed splint. Figure 5D displays over-taping causing a blockage of air flow through the 3D-printed splint, and Figure 5E shows light taping to secure the splint and allow airflow. Despite over-taping being a possible cause to the 3D-printed splint feeling hot at times, the material used for 3D printing of mallet splints needs addressing in relation to warping and airflow.

Patients commented that not having to use tape to secure the 3D-printed splint would have been an added bonus as trying to secure the splint alone can be cumbersome. One patient did not wear tape throughout the study and did not experience the splint falling off. However, nine out of ten patients wore tape throughout to secure the splint.

3.6. Patient quotes

Regarding the generic Stack splint, one patient commented that it “*wasn’t much good*” to them. The patient found it “*clumsy, too big*” and that it got “*caught in clothes and bed clothes*” while performing activities of daily living (ADLs). The patient also reported that the 3D-printed splint, although much improved and being a better fit, was “*sweaty*” and “*needed more ventilation.*” Patients commented that the Stack splint seemed “*better ventilated as [sic] had holes*” and “*felt more airy.*”

Patients commented that wearing either splint throughout the day was difficult in relation to performing ADLs. Many found wearing a glove useful to keep the splints dry. However, they noted the need for “*extra care removing the glove as [sic] can pull the splint away.*” They also noted that it “*increases sweating.*”

Some patients commented that on hot days, or when busy using their hands, their injured finger could swell at times. In relation to the generic Stack splint, they said “*as this didn't fit well, I had space to swell.*” Conversely, in relation to the custom-fit 3D-printed splint, they said “*there was less space to swell so it could feel tight at times.*”

Part of the recovery for mallet injury involves flexing the PIPj. Allowing and encouraging flexion of the PIPj reduces difficulty with range of movement and recovery when the splint is removed. It also improves functional use of the hand during the DIPj immobilization period. Patients commented that they felt a much better range of movement with the 3D-printed splint than the Stack splint. Patients also commented that they “*couldn't bend the finger at all*” with the generic Stack splint because “*it was too long*” and covered the joint.

4. Discussion

This research uncovers a clinical benefit, albeit in a small cohort. This was a pilot study involving ten patients. Future studies assessing statistical aspects should consider the power of such study to ascertain the number of patients. Patients successfully recovered using the 3D-printed splint as evidenced by the Crawford classification scale used by the OT. The findings—40% of patients made an excellent recovery and 40% made a good recovery—are promising. This is the first study to show a clinical benefit by supporting multiple patients in their recovery from mallet injury using a 3D-printed mallet splint.

The study also shows an acceptance of a 3D-printed mallet splint. Both patients and an OT confirmed they would use the splint again if needed, with modifications. These findings are encouraging and are helpful to expand research in the use of 3D printing for mallet finger injuries going forward. However, it is important to note that mallet finger injuries tend to swell mostly during the first week of injury, thus a generic Stack splint was used during that period in the current study. Patients may have reported relief on the fitting of the 3D-printed mallet splint due to a reduction of swelling and not solely due to the bespoke fit.

Key areas of focus in this study were measuring finger dimensions, patient requirements, design of the 3D-printed splint, patient discharge advice and compliance, and process. These are discussed in the following section along with key findings and recommendations for further research.

4.1. Measurements of finger dimensions

Calipers were used to measure each patient's finger anthropometrics because they were available to the research team and are an accurate measuring method. Moreover,

they do not require specialized computer equipment, which would have been impractical in this clinical setting at least.²⁴ Patients were recruited from three different hospital sites, and this would have necessitated three scanning devices and associated computing requirements. 3D scanning could certainly have a role in bespoke splint design, and further studies should consider this.

4.2. Patient requirements

Mallet injuries require patients to be highly involved and dedicated to their recovery. A splint immobilizes the area to promote healing; however, patients must follow strict discharge guidelines, adhere to hand hygiene, and complete the treatment time. In this study, every patient had experience of both a generic Stack splint and the 3D-printed splint within the same treatment period. Therefore, the ratings of both splints are not just accurate, and they are immediate when the generic Stack is changed to the 3D-printed splint. The 3D-printed splint was applied approximately 7 days after the initial injury. Because the injured finger typically swells during the first 7 days post-injury, it could be argued that the 3D-printed splint was applied at a less swollen and painful time in the patient's recovery. However, the custom fit was a welcome change, affording more comfort, and reducing skin maceration and blistering experienced with the generic Stack splint. Once the 3D-printed splint was fitted, incidence of maceration and blistering was reduced. Patient feedback highlighted some modifications to improve the 3D-printed splint.

4.2.1. Design of splint

The design of the 3D-printed splint aimed to support the healing of the mallet injury while ensuring comfort of using and clinical soundness of the splint. The outcomes of the study are positive clinically, but the following areas were highlighted for improvement: (i) air flow, (ii) securing to the finger, (iii) giving clearance to the PIPj, and (iv) material used.

Modern Stack splints are regularly perforated to allow air flow and increase comfort. Perforations were not included in the 3D-printed splint for this study at the request of the clinical expert who, based on their experience, felt perforations in the splint encourage swelling through the small perforations and can add to skin complications. Instead, a gap was left along the length of the splint to allow for airflow. Patients who found the 3D-printed splint too hot had placed tape around the circumference of the splint and over this gap. Patients who placed a thin layer of tape at the base of the splint reported no issues with airflow. Ventilation is a key element for comfort and to protect the skin. The design therefore needs to evolve to best facilitate

airflow. In addition, discharge advice on how best to secure the 3D-printed splint is essential and needs more focus.

4.2.2. Securing to the finger

Although one of the goals of the initial design was to minimize the use of adhesive tape to secure the splint, patients generally preferred the additional security provided by tape. Patients had been securing the generic Stack splint with tape for several days before wearing the 3D-printed splint and felt more secure continuing with tape. However, the amount of tape required to secure the 3D-printed splint was notably less than that required for the generic splint. It is important to consider designing a splint that does not require any extra taping to make it easier to remove and reapply.

4.2.3. Materials

Patients also reported that the 3D-printed splint fit well on initial application. However, over the 8 weeks, some patients reported that the splint began to change shape, losing its form and distorting. This led to increased use of tape to ensure the splint stayed in place. The distortion can be attributed to the mechanical properties of the 3D printing material and is an important finding for future design iterations. The material needs to be robust and durable enough to last the duration of the treatment. Further research is needed to determine what material to use.

4.2.4. PIPj

It is necessary to keep the PIPj free to flex during mallet finger treatment.¹² Only the DIPj needs to be immobilized. Therefore, when designing a splint for mallet finger treatment, it is essential to allow enough clearance between the base of the splint to the PIPj. Focusing on each patient's anthropometrics as the study progressed ensured the PIPj had adequate clearance to move freely.

In addition to some modifications needed for the 3D-printed splint, the process used for this study worked well as a research study but needs careful consideration to be made logistically possible in healthcare facilities. Currently, generic Stack splints are the most common offering for treatment of mallet finger injuries. One unit in the ULHG provides custom splinting from the OT team on a limited basis. Although the 3D-printed splint was found to be more acceptable to patients in this study, there are barriers to the roll out of this service across healthcare units.

4.3. Process challenges

Based on the findings of this small pilot study, the introduction of 3D-printed mallet splints for patients in hospitals would appear to be a welcome treatment option.

Patterson et al. report that the use of 3D printing in hand therapy is still very much in its infancy.³⁰ They attribute this to the absence of purpose-built software programs for splint design. There is, therefore, a considerable learning curve for healthcare practitioners to become proficient in designing splints.

There are many steps required to bring this 3D-printed splint option to patients. The development of 3D printing technologies has progressed at a rapid pace since its introduction in the late 1980s. Regulation on the use of 3D printing for healthcare applications is often unclear.³¹ However, some guidance is forming; ISO 52910 outlines guidelines on the use of additive manufacturing in product design and is applicable to all products fabricated by any type of additive manufacturing.³² Until this guidance is clear and appropriate for medical applications, the use of 3D printing outside of research studies will be curtailed. Nonetheless, it is important to discuss key steps in the process to help visualize a future for 3D printing for mallet finger injuries in hospitals.

One area this study highlighted as challenging is the immediate need for a custom 3D-printed splint to treat a patient. Patients presenting at hospital with a mallet injury require timely treatment. The procedure in this study involved first applying the generic Stack splint to each patient for a number of days to allow the research team time to coordinate the measuring, printing, and fitting of the 3D-printed splint. As a measuring technician is not based in each unit, and the appropriate 3D printer is not present in each unit, some additional steps would be needed to offer an immediate 3D-printed mallet splint.

4.4. Discharge advice and compliance

There are many studies detailing how patients are often discharged without a clear understanding of their discharge advice.³³⁻³⁵ This can lead to confusion, frustration, poor compliance, and clinical complications for patients.

Mallet injuries require patients to closely follow their discharge advice to support their recovery. It is therefore essential to provide clear, concise discharge advice to ensure patients can care for their injury while at home. It is equally important to ensure patients understand the advice given.

A study conducted by Groth et al. looked at the impact of compliance on the rehabilitation of patients with mallet finger injuries.³⁶ They revealed that compliant patients have excellent outcomes more often than non-compliant patients (61.5% and 9.1%, respectively). Two of the patients enrolled in this study did not comply with discharge advice. One removed the splint before completing their treatment,

and the other bent the finger throughout the course of the study. This was an unfortunate misunderstanding and one that reinforces the importance of ensuring patients fully understand how to care for their injury before being discharged.

4.5. Implications of findings

This pilot study has shown a clinical benefit of 3D printing splints to treat mallet injuries, albeit in a small cohort. Within the Irish healthcare system, custom splinting is not widely available because specialist roles are not broadly in place. This leads to delays in custom splinting, or patients being provided with a generic Stack splint for the duration of their treatment.

This study provides initial evidence to support custom splinting for hand injuries, emphasizing that patients deserve custom splinting to support healing, comfort, and recovery from their injuries.³⁷ Using 3D-printed bespoke mallet splints provides a custom fit and therefore improves access to custom care that is otherwise currently limited. To that end, offering 3D-printed mallet splints in EDs and IUs should be considered. By expanding research beyond the current offering of feasibility and pilot studies, a focus on clinical outcomes of 3D-printed mallet splints on a wider scale could provide the data-driven evidence needed to change the current healthcare splinting options.

4.6. Future work

There are some further research considerations arising from this study. Patient and clinician acceptance along with clinical efficacy were the key areas of focus for this pilot study. One consideration is the cost implications of 3D-printed mallet splints versus generic Stack splints. A health economics review of the resources, equipment, and infrastructure required to implement 3D printing of mallet splints is beyond the scope of this current study, but future studies should consider this. Other areas for further consideration include:

- An optimal method to measure mallet fingers for 3D printing
- The ventilation of 3D-printed mallet splints
- Methods of securing the splint
- Finding the optimum 3D printing material for use in the printing of mallet splints
- Defining the process for providing 3D-printed mallet splints outside the research realm

5. Conclusions

This study aimed to evaluate the clinical outcome along with patient and HCP acceptance of bespoke 3D-printed

mallet splints for the treatment of mallet finger injury. The patients and a specialist hand OT felt that they would use the 3D-printed splint over the generic Stack splint if needed again. 3D printing has been demonstrated as a viable method for producing bespoke devices for patients with mallet injury, albeit on a small scale. There is potential for 3D printing to produce mallet injury splints, which could provide an enhanced clinical offering over traditional splinting methods. By using patient-centered, bespoke 3D printing capabilities, the management of mallet injuries can be improved and custom splinting offered to a wider population.

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Conflict of interest

The authors declare no conflicts of interest.

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Ethics approval and consent to participate

This study was approved by the Research Ethics Committee of ULHG (Reference 087/2022). Written informed consent was obtained from all participants prior to the study.

Consent for publication

Patients were given and requested to read Patient Information Leaflets before signing consent forms.

Permission was obtained from each of the subjects to *publish* their data and images.

Availability of data

The data that support the findings of this study are not openly available but are available from the corresponding author upon reasonable request. Data are located in controlled access data storage at the University of Limerick.

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