SYSTEMS-LEVEL QUALITY IMPROVEMENT

Lightweight Splint Design for Individualized Treatment of Distal Radius Fracture

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Abstract

A systematic design approach is proposed for medical splints for individualized treatment of the distal radius fracture. An initial split structural model is first constructed by 3D scanning of an injured limb. Based on the biomechanical theory and clinical experiences, the topology optimization method is applied to design the splint structure. The optimized lightweight splint is realized by additive manufacturing using polylactic acid. Compared to the traditional designs for the distal radius fracture, the optimized design by the proposed approach exhibits a weight reduction of more than 40%. Besides, the mechanical properties of the splint meet the requirements of medical treatment according to the simulation results. Numerical examples are provided to demonstrate the applicability of the approach.

Keywords Lightweight splint · Distal radius fracture · Topology optimization · Individualized treatment

Introduction

Distal radius fracture(DRF)is one of the most common types of fractures and the patients number appears to be increasing every year worldwide [1]. The conservative treatment of closed reduction and casting has historically been the mainstay of treatment for distal radius fractures. In the process of clinical treatment, splint is used to immobilize radius and ulnar deviation. The anti-inflammatory drugs are also applied to alleviate the inflammation. However, the traditional distal fracture splint made by gypsum or plastic is bulky, heavy and discomfort. The heavy splint structure tightly covers a large area around the injured surface skin, making it difficult to contact with the air and to be cleaned. The morbidities associated with conventional splints may result in cast complications such as malunion, bone and joint injuries, or cutaneous diseases [2, 3]. In order to remove the redundant material and improve ventilation, more and more design and manufacturing methods are put forward and new splints are designed these years.

Monireh A Bani designed a custom-made splint for the patients with Osteoarthritis of the first carpometacarpal. During the period of comparative clinical trials, the pain of the patients with custom-made splint decreased and the grip strength, pinch strength and the function are increased [4]. Fernando Blaya proposed a method of designing distal radius fracture splint by utilizing 3D digitalization techniques and reverse engineering software [5]. David Palousek described the utilization of rapid prototyping (RP), passive stereo photogrammetry and software tools for the distal radius fractures design process. The approach was based on specific technologies, such as 3D digitizing, reverse engineering and polygonal-surface software, FDM RP and 3D printing. However, this work did not take the

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Fig. 1 Creative design flow of individualized lightweight splin
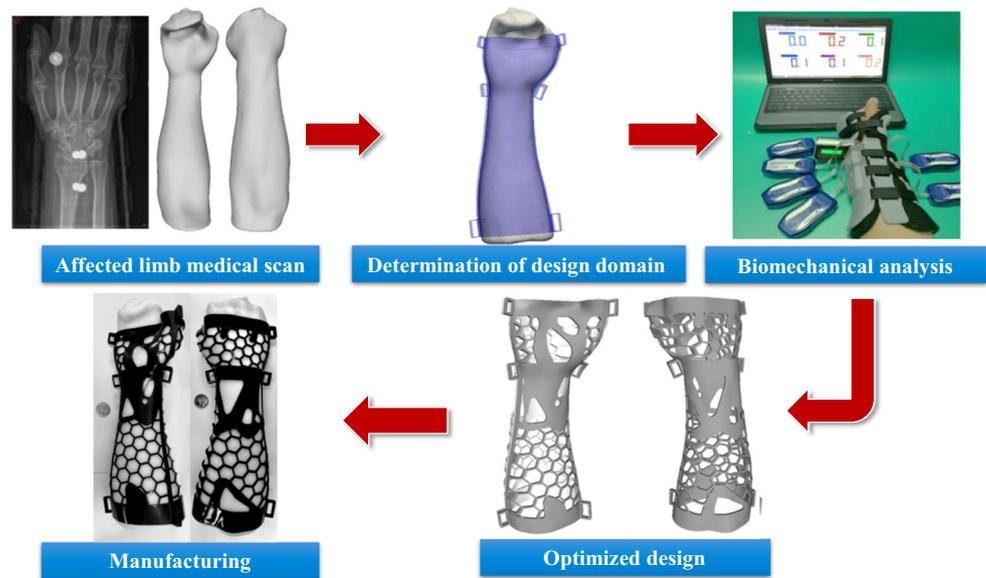
fixing effect of the splint into account and verify the performance of the splint [6].Tz-How Huang designed a new splint according to the shape of traditional splint by the finite element simulation and topology optimization. Although the splint wraps a large area of affected limb skin, which makes the limb difficult to ventilate as well as to be washed regularly [7].

Since Bendsøe [8] firstly proposed the concept of topology optimization, this technique has been developed remarkably over the last several decades [9–12]. At present, topology optimization plays an important role in aviation, aerospace and many other high-precision fields, topology optimization has been widely employed as an effective means for structural lightweight design [13–15]. It intends to find the optimized material distribution in the design domain within the given optimization objectives, constraints and boundary conditions. It is based on iterative simulation and design optimization process which can automatically obtain the optimized design that meets the design requirements. Compared with the traditional structural design methods, the design cycle is shorter and the design cost is much lower. Mingdong Zhou proposed a Constructive Solid Geometry based Level Set description to represent the structure based on two types of basic entities. By the method, the optimized design with engineering feature can be created finally [16]. Mingdong Zhou proposed a density based topology optimization method with a minimum length scale constraint. The final design can possess the user-specified minimum length scale to avoid the existence of too small structure in the structure and make it difficult to manufacture [17]. Liao YC [18] proposed a novel design of the Boston brace with topology optimization by using the finite element method. They found that this method can effectively estimate

redundant material distribution and accordingly custom-design a lighter brace without any loss of its corrective effect. These achievements also motivate further studies and applications of topology optimization in the splint design.

Besides, Additive Manufacturing also provides effective means to realized topology optimized medical equipment. Aitor Cazon [19] manufactured a porous splint with clamping and fixing function by additive manufacturing method. The results of experiment shows that under the low severity loads, the displacement in the main loading direction is smaller than that of the traditional type, which is fabricated by hand from low temperature thermoplastic.

Fig. 2 X-ray of patients with distal radius fracture

Fig. 3 Forearm arm scan model
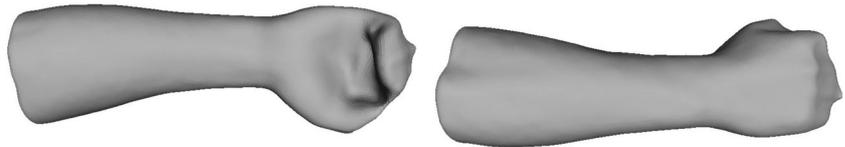
In this paper, based on the biomechanical theory and previous clinical experiences, a systematical design and manufacturing workflow of splint for distal radius fracture based on the topology optimization method is proposed. In addition, the porotype is manufactured by fused deposition manufacturing.

Materials and methods

In this section, a generative design workflow of individualized light splint is introduced for the clinical cases of distal radius fracture. The properties of material, which are used in the process of simulation and analysis, are set according to the material used in the 3D printing. As shown in Fig.1, the design and manufacturing process of splint is composed of the following five steps:

(1). In view of the typical clinical cases of distal radius fracture, the injured limb model is obtained by medical scanning.
(2). Based on the injured limb model, the design space of splint structure is defined with a design domain and a non-design domain.
(3). According to the clinical experiences and biomechanical theory, the positions and directions of the main loads acting on the injured limb in the process of treatment are analyzed. The values of the loads in each position are measured.
(4). The lightweight individualized splint is designed by topology optimization to have the desirable mechanical properties, wearability and to meet geometric requirements of the splint.

(5). The finite element method is used to simulate and analyze the performance of the optimized structure. Finally, the splint structure is fabricated by additive manufacturing.

Material properties of the thermoplastic

The PLA is a biocompatible and recyclable material, hence skin reaction and irritation can be prevented. On the other hand, a recyclable splint made by PLA can suppose a great reduction of pollution and cost.

On the other hand, the technology of using PLA as the material for 3D printing has been mature and widely used [20]. In the process of simulation and design, the elastic modulus and the Poisson's ratio of the material is set to 2636 MPa and 0.3 according to the test report about material properties provided by Polymaker (https://polymaker.com/product/polylite-pla/).

Construction of forearm arm model

In order to obtain an initial model of distal radius fracture, a 57-year-old male patient in Shanghai Ruijin Hospital is selected for the medical scanning of the injured limb (Fig.2). The patient's injured limb had undergone the swelling stage, when he received basic treatment with traditional splints [20]. In order to have the best therapeutic effect, the patient's wrist is in a relaxed state of dorsal flexion, and the position from the end of the finger to the elbow joint is scanned with the medical scanner of hospital is used to scan the injured limb. A model of the injured limb in Stereolithographic (STL) format, shown in Fig.3, is constructed from the scan data.

(a) (b) (c)
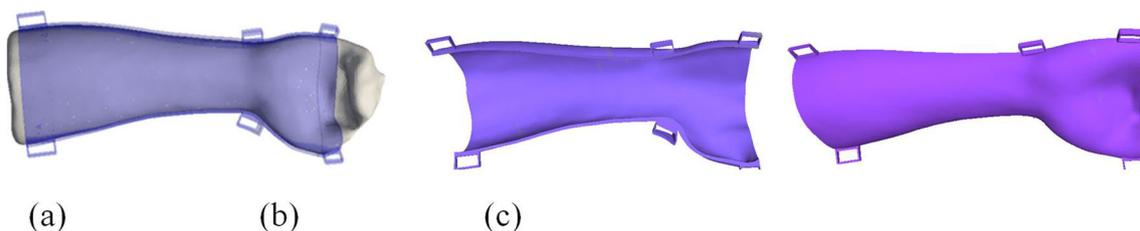
Fig. 4 Initial guess of splint: (**a**) combination of splint initial design and injured limb model (**b**) left half of the initial guess, (**c**) right half of the initial guess

Fig. 5 The design domain and the non-design domain

(a) non-design domain   (b) design domain
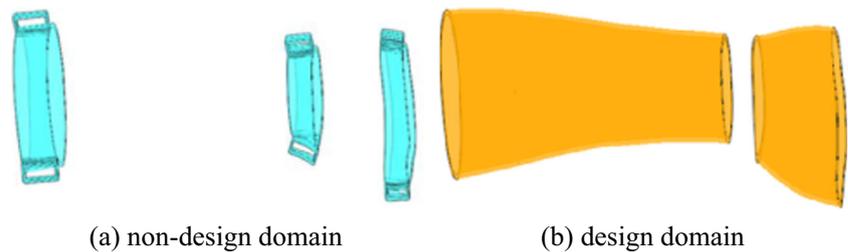
To meet the comfortability requirements of the patients' daily wear, the initial design structure of the splint with 3 mm wall thickness is constructed according to the external contour of the injured limb model, as shown in Fig.4. The width of the each of them is 2 cm and as same as the width of each convex ring structures. This initial design consists of front and rear parts, which are fixed on both sides by winding a convex ring structure with a bandage. According to the fixation mode of the splint structure as well as the force distribution of the injured limb during the treatment process, the initial guess of the splint is divided into a design domain and a non-design domain as shown in Fig. 5.

Biomechanical analysis

According to the clinical experience of using the traditional splint as shown in Fig.6 and the biomechanical theory [18], the contact pressures of each main points on the arm are first measured as shown in Fig.7. The patient is recruited for the acquisition of forearm mechanics information by wearing a traditional splint according to the treatment plan. The membrane pressure sensors are affixed to 22 points that composed of the key positions of anatomy, the sensitive position of pain nerve, the key positions of the proximal end and the distal end of fracture line (Fig.8). Each pressure sensor is 0.20 mm thick, 152 mm long and 14 mm wide. For the contact pressure of all the measure points, the mean value of three

experiments is chosen as the applied force. The upper and lower limits of the pressure at each point are set according to clinical experiences [21] as shown in Table 1.

After acquiring the force information on the splint, the simulation of the mechanical properties of the splint are done by the Radioss based on the finite element method [22]. As shown in Fig. 9, a mesh of tetrahedron solid elements is generated for the initial split structure.

The forces shown in Table 1 are applied on the corresponding position in the normal direction of the splint surface, as shown in Fig.10. Besides, the non-designable parts are assumed as fixed boundaries.

The displacement distribution of the structure is shown in Fig. 11, where the maximum displacement of the structure is 0.13 mm. The value is much smaller than the maximum allowable displacement of the medical splint, which is 2.5 mm according to the clinical experiences provided by Ruijin Hospital, indicating that a large number of material can be removed for a lightweight design under the premise of satisfying the medical treatment requirements.
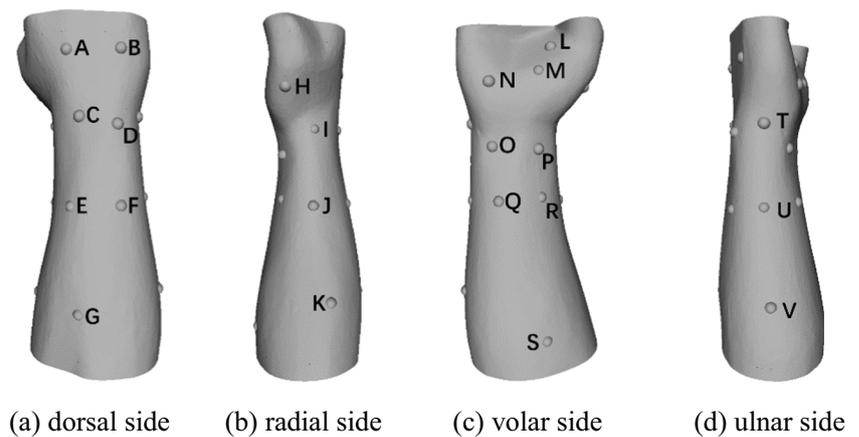
Topology optimization

In this work, the topology optimization method [23] is leveraged to design a lightweight splint structure and improve the performance of it compared to the traditional design. The essence of topology optimization is a material distribution method in a prescribed design domain by minimizing the certain

Fig. 6 Traditional splint for distal radial fracture

(a) dorsal side   (b) radial side   (c) volar side   (d) ulnar side

Fig. 7 Force measure points on the forearm model

(a) dorsal side   (b) radial side   (c) volar side   (d) ulnar side

optimization objective and fulfilling a set of constraints. During the last several decades, it has become immensely popular and been applied to a wide range application areas apart from the original mechanics problems. The workflow is shown in Fig.12 as follows:

Selecting the appropriate kind and number of element to mesh the initial guess of the structure to be optimized is the premise of applying the topology optimization method based on the finite element method. After the construction of the finite element model, the boundary conditions are set up according to the actual working conditions. The main part of the topology optimization is composed of the construction of the physical model of the structure, the definition of topology optimization problem and the iterative calculation based on optimization theory. By the method of structural parameterization, the discrete finite element model in space can be transformed into a continuous model whose topology can be changed continuously. The optimization problem, which includes the optimization objective and constraints, is set up according to the design requirement. After that, the derivative

of the objective function and constraint function, which are formed according to the optimization problem, are used by the optimizer to search the optimized result in each iteration. After several iterations, the optimized design is generated when the convergence conditions are satisfied. Finally, the model of optimized design is provided for manufacturing by the post-process.

The finite element model and boundary condition are introduced in the above two sections. The structural parameterization of the design case is based on the standard "density based approach to topology optimization", where a set of

Fig. 8 Acquisition of forearm mechanics information

Table 1 The size of the force in the marker

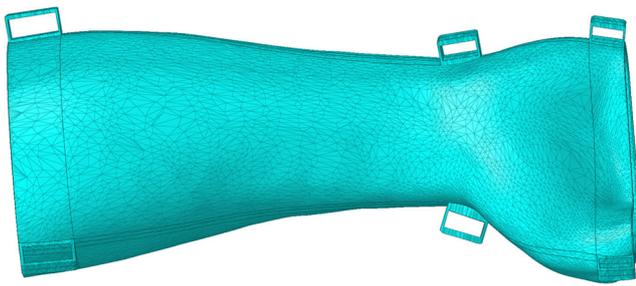| Position	Force (N)
A	34.77 ± 0.24
B	13.42 ± 0.01
C	18.91 ± 0.07
D	90.28 ± 0.12
E	48.19 ± 0.08
F	34.16 ± 0.01
G	54.29 ± 0.27
H	68.32 ± 0.56
I	86.01 ± 0.51
J	73.81 ± 0.07
K	95.16 ± 0.13
L	31.72 ± 0.08
M	73.81 ± 0.09
N	92.11 ± 0.29
O	3.66 ± 0.01
P	63.44 ± 0.27
Q	34.16 ± 0.02
R	53.07 ± 0.02
S	39.04 ± 0.18
T	48.19 ± 0.21
U	32.94 ± 0.04
V	26.84 ± 0.02
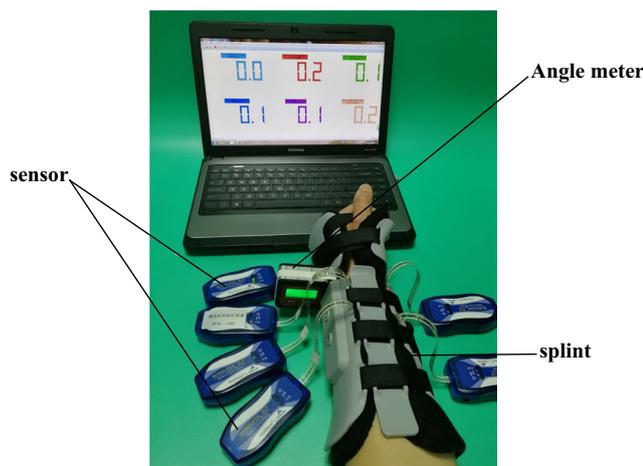
Fig. 9 Finite element mesh model

design variables ρ represent the piece-wise constant densities of the elements who discretize the initial guess model of the splint structure. The value of the design variable represents the proportion of material in each element and ranges from solid ρ = 1 to void ρ = 0 in each element. Thus, by defining the value of each element's design variable, the structure discretized by elements and consisting of material in the space can be defined.

In order to give physical meaning to the above-mentioned forms of existence of materials based on man-made assumptions, the material is considered as linear isotropic in the work and the elastic modulus E_e of each element is the function of

Fig. 10 Boundary conditions

the design variable which is given by the modified simplified isotropic material with penalization (SIMP) [24] interpolation scheme:

$$E_e = E(\rho) = E_{min} + \rho^P(E_0 - E_{min}) \qquad (2-1)$$

where P is the penalization power, E_{min} is a non-zero value in order to avoid the singularity of the stiffness matrix and E_0 is the Young's modulus of solid material($\rho = 1$).

In this work, the topology optimization method based of SIMP method is applied to minimize the energy of compliance, which is equivalent to maximizing the stiffness of the splint. The optimization constraint it subject to is satisfying the requirement of structural volume at the end. The standard mathematical formulations of the above optimization problem is defined as follows (2-2).

$$
\begin{aligned}
\min_{\rho} : & \; f(\rho) = U^T K U = \sum_e u_e^T k_e u_e \\
s.t. : & \; KU = F \\
& : g = V(\rho)/V^* - 1 = \sum_e v_e \rho / V^* - 1 \leq 0 \qquad (2-2)\\
& : 0 \leq \rho \leq 1
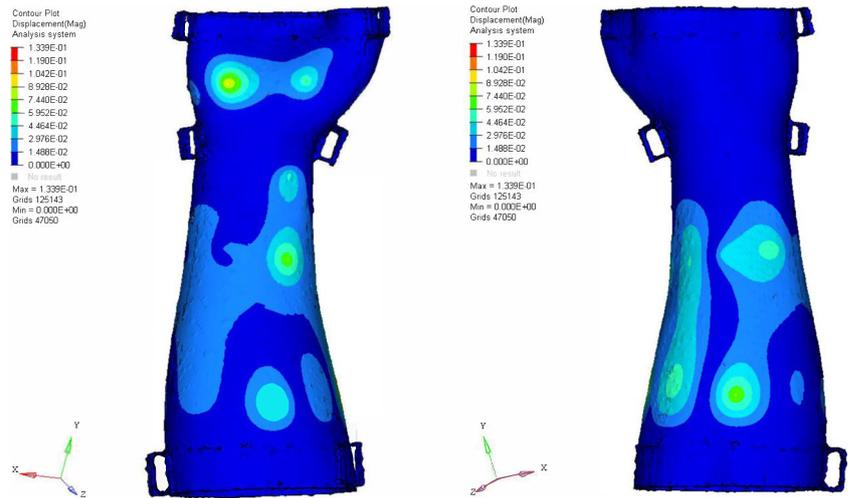\end{aligned}
$$

(a) Forces are loaded on the corresponding nodes
in the normal direction of the splint surface
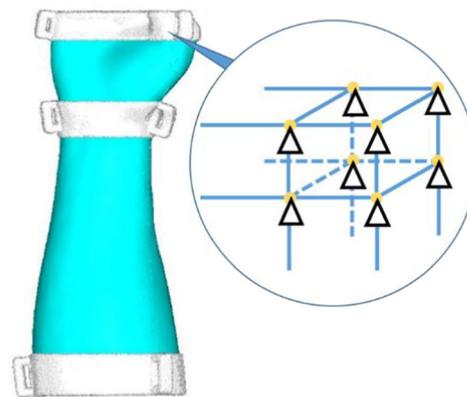
(b) All the freedom degrees of nodes in the non-design domain are constrained

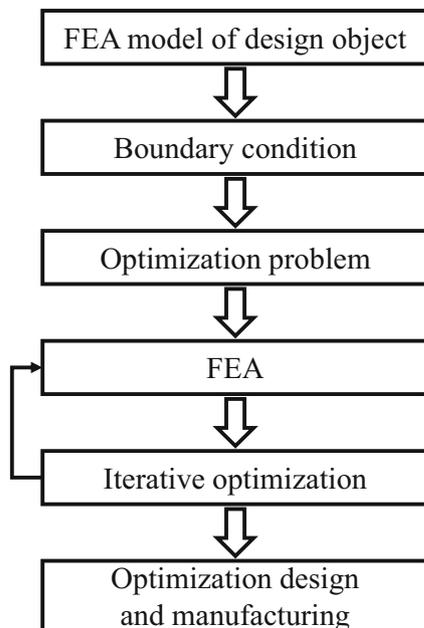**Fig. 11** Displacement distribution of the design space with the boundary condition

where K is the global stiffness matrix, U is the global displacement vector, F is the global force vector and the lower case symbols indicate the element-wise quantities, $k_e = k(\rho) = E(\rho)k_e^0$ is the element stiffness matrix and k_e^0 is the element stiffness for solid element. $V(\rho)$ indicates the summation of the all elements' volume, V^* is the material constraint and u_e is the volume of each element.

A gradient based optimization algorithm, the method of moving asymptotes (MMA) [25] is leveraged to obtained the optimized design, with the sensitivity provided as follows,

$$\frac{\partial f}{\partial \rho} = -u_e^T \frac{\partial k_e}{\partial \rho} u_e$$

$$\frac{\partial k_e}{\partial \rho} = P(E_0 - E_{min})\rho^{p-1}k_e^0 \qquad (2-3)$$

$$\frac{\partial g}{\partial \rho} = v_e / V^*$$

Taking a cantilever beam with the same optimization problem as an example. The design domain's dimensions and the boundary conditions are shown in Fig. 13a. The design domain is discretized with bi-linear quadrilaterals. The Young's modulus of solid material is $E_0 = 1$ and the minimum positive value $E_{min} = 10^{-9}$, the Possion's ratio is $v = 0.3$ and the penalization factor is $P = 3$, the volume constraint $V(\rho)/V^* = 0.5$. After the process of density based topology optimization, the optimized light weight cantilever beam is shown in Fig. 13b.
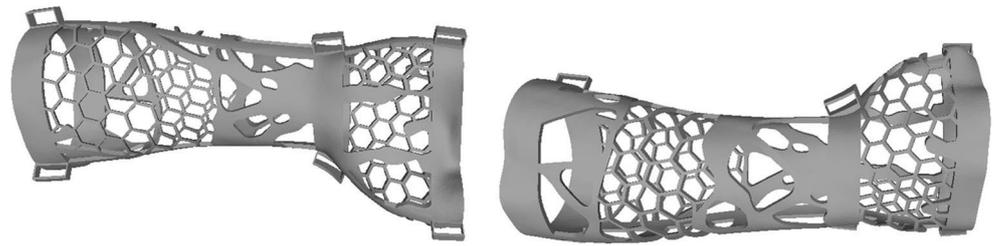

Fig. 12 Flowchart of topology optimization

(a) Boundary conditions and size of cantilever beam

solid element

intermediate density element

void element
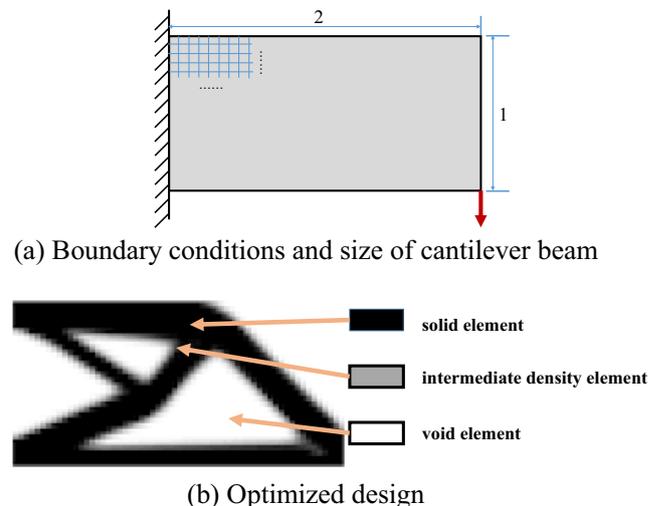
(b) Optimized design

Fig. 13 Lightweight design of a cantilever beam

Fig. 14 Optimized splint model

Results

Optimization of splint structure

In order to improve the accuracy of finite element analysis and the property of the optimized design, we use 2,254,225 one-order solid hexahedral elements to mesh the design space of splint. After applying the boundary conditions introduced in section2.2, several different values of volume constraint are used to optimize the splint. By comparing the weight and stiffness of each result, the final optimized design is selected among them. The model of splint after the post-process is shown in Fig. 14.

Verification and prototype

In order to evaluate the physical properties of the lightweight splint design, the finite element method is used to perform the verification. With the above mentioned boundary conditions, the displacement distribution of the splint model is shown in Fig. 15.

The finite element simulation results show that the maximum displacement of the structure is 1.00 mm under the boundary condition. The deformation of splint is in

accordance with the medical requirements, and the deformation of the splint is mainly located far from the injured part, which meets the requirements of clinical treatment.

In this work, PLA is used to manufacture the splint structure by fused deposition manufacturing. In order to accelerate the manufacturing speed and reduce the material cost, the two splint parts are printed in turn (Fig. 16).

In the process of printing, PLA is used to print the model, and the water-soluble material polyvinyl alcohol (PVA) is used to print the supporting structure to avoid the collapse caused by overhang. The two print files are generated separately, and the printing parameters such as the temperature of the bottom plate (60 °C) and the temperature of the print heads, whose calibers are 0.4 mm, are set according to the requirements of each material (PLA:200 °C and PVA:215 °C). In order to avoid thermal warping of the whole structure in the printing process and reduce the cost of material, the filling ratio of splint structure is 100% and that of supporting structure is 30%. The layer height is set to 0.1 mm and the print speed is set to 70 mm/s. The rest of the printing parameters refer to the default values provided by the database of software. The final prototype is fixed with three medical straps as shown in Fig. 17.

Fig. 15 Displacement distribution map
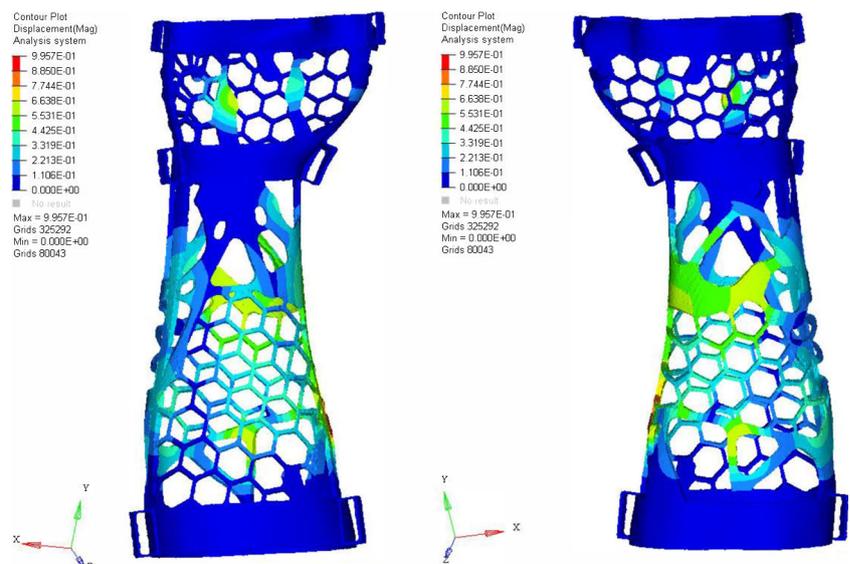
Fig. 16 Splint models printed separately
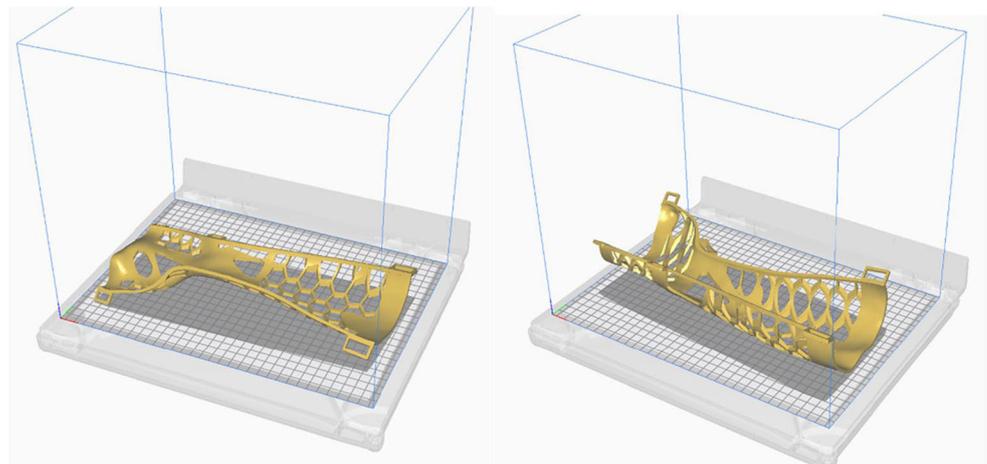
Fig. 17 Optimized splint worn on arm model

The mechanical properties and physical properties of the splint structure designed in this work are compared with those of the full material splint and the traditional traction splint composed of composite polyethylene as shown in Table 2.

As shown by the simulation results, the total weight of the splints designed in this work are more than 40% less than that of the traditional traction splint, and the maximum displacement of the structure meets the medical requirements for corresponding treatment schemes.

Discussion

This paper provides a systematic topology optimization based design approach to design lightweight and porous splint for distal radius fractures.

Compared with the traditional design, more than 40% of the redundant material of splint is eliminated in the work. The porous splint structure makes it possible for the affected limb to be in contact with the air, thus to avoid the related complications. At the same time, it is convenient for the patient to clean the affected limb while wearing the splint. In addition, as a kind of orthopedic treatment equipment for immobilization, the holes in the splint make it possible for the doctor to monitor the condition of the affected limb in real time. The individualized light splint, which is designed by topology optimization, provides an enlightening new idea for the design of medical splint structure. The proposed method can be combined with fast prototyping technique to improve the efficiency of treatment as well as to ensure the therapeutic effect. Furthermore, the design method can be used not only for the distal radius fracture splint but also for the design of other medical devices such as external bones.

However, the design method raised in the work, which provides an optimized splint structure, contains certain assumptions. The non-design domain part of the splint designed in this design method is assumed to be fully bonded and fixed with the skin, but the micro-motion does exist in the actual wearing process. In the finite element analysis, the applied

Table 2 Comparison among the splints' performances

Splint type	Weight(g)	Weight loss ratio	Maximum displacement(mm)
Traditional splint	235	/	1.42
Full material splint	248	0%	0.13
Optimized splint	136	42%	1.00

force is assumed to be the node force along the normal direction, but the actual force is often distributed in different directions.

In the next stage, it is necessary to improve the model of the working condition of splint according to the clinical testing. Functional mechanisms such as the traction module can be designed and added to the splint to improve the therapeutic effect.

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