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تصميم صفائح تثبيت طرفي العظم مع تقليل تأثير الحماية من الإجهاد باستخدام تحسين الطوبولوجيا

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* توضع علامة النجمة فوق اسم الباحث الذي تتم المراسلات معه بغض النظر عن الترقيم او ترتيب الاسماء (كباحث رئيسي – طالب دراسات عليا)

الملخص:

يعرض المقال تحليل تأثير الحماية من الإجهاد (SSE) في صفائح تثبيت طرفي العظم، وآثاره الضارة على شفاء كسور العظام والحلول الممكنة لتقليلها. لقد تبين أنه يمكن تقليل SSE باستخدام ألواح مصنوعة من مواد ذات معامل مرونة منخفض (سبائك التيتانيوم، والبوليمرات القابلة للامتصاص الحيوي، وما إلى ذلك) أو عن طريق تحسين شكلها الهندسي. يتم تحليل الاحتمال الأخير بطريقة أكثر تفصيلاً مع التركيز بشكل خاص على تحسين الطوبولوجيا (TO) كأداة تحسين جديدة نسبيًا تستخدم على نطاق واسع من قبل مجتمع الهندسة الطبية الحيوية. كمثال عملي، تم تطبيق TO باستخدام برنامج Comsol Multiphysics لحل مشكلة التصميم ثنائي الأبعاد صفائح تثبيت طرفي العظم. لقد تبين أن الصلابة الطولية للوحة المحسنة يمكن تقليلها بنسبة تصل إلى ٨٤٪ مقارنة بالتصميم الأولي غير الأمثل اعتمادًا على قيمة التخفيض الموصوف للوزن المستخدم كقيد أثناء التحليل. يوضح التصميم الأمثل زيادة في الحد الأقصى لإجهاد فون ميزس، لكن التوزيع العام للضغوط يصبح أكثر اتساقًا مقارنة بالتصميم الأولي. يمكن تصنيع النموذج الأولي للصفيحة المحسنة بسهولة باستخدام القطع بالليزر أو آلة التفريغ الكهربائي للأسلاك.

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Design Of Osteosynthesis Plates With Reduced Stress Shielding Effect Using Topology Optimization

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Received:
Accepted:

Abstract:

The article presents analysis of stress shielding effect (SSE) in osteosynthesis plates, its adverse effects on healing of bone fractures and possible solutions for its minimization. It is shown that SSE can be reduced by using plates made of materials with low elastic modulus (β titanium alloys, bioresorbable polymers etc.) or by optimization of their geometric shape. The latter possibility is analysed in a more detailed way with special accent on topology optimization (TO) as a relatively new optimization tool widely used by biomedical engineering community. As a practical example, TO using Comsol Multiphysics software is applied to solution of 2D design problem of osteosynthesis plate. It is shown that longitudinal stiffness of optimized plate can be reduced up to 84 % relative to initial non-optimized design depending on the value of prescribed reduction of weight used as constraint during analysis. Optimized design demonstrates increase in maximum von Mises stress, but overall distribution of stresses becomes more uniform in comparison with initial design. Prototype of optimized plate can be easily manufactured using laser cutting or wire electric discharge machining.

Keywords: Osteosynthesis Plates, Stress Shielding Effect, Topology Optimization

1. Introduction:

Bone fractures are among the most frequently encountered injuries in the world with more than 150 million cases each year. Surgical treatment of bone fractures is based on application of osteosynthesis (bone fixation) plates connected to the bone fragments using screws and ensuring stable relative position of the fragments necessary for their healing. Today bone fixation plates are produced in a wide range of designs depending on anatomical position of fracture, method of fixation and other factors. However, development of new designs of osteosynthesis plates remains actual engineering and medical problem, especially with account for the growing interest in personalized medicine: it is obvious that efficiency of fracture treatment will benefit from application of patient-specific designs of fixation plates considering individual anatomical peculiarities and biomechanical properties of the patient's bones.

2. Literature Review:

One of the main problems related to the use of osteosynthesis plates is so called stress shielding effect (SSE) (Dai, 2004; Gilbert, 1988): application of rigid fixation plates results in protection (shielding) of bone tissue from mechanical stresses typical for healthy bone. SSE can produce adverse effects during fracture healing, particularly osteopenia – reduction of biomineral density (BMD) and strength of bone. Osteopenia related to SSE is a direct consequence of Wolff's law stating that microstructure, biomechanical properties and gross morphology of bones are adapted to the changes in external loads acting on them (Ahn & Grodzinsky, 2009; Boyle & Kim, 2011; Frost, 2001). Wolff's law is derived from the observation of German surgeon Julius Wolff, who found out that trabecular bundles in femur bone are directed along the trajectories of principal mechanical stresses. Adaptation of bone to the external loads is more thoroughly described by so called Utah paradigm stating that mechanical stresses produced in bone tissue by these loads are detected by mechanically-sensitive cells (osteocytes) and compared to the prescribed threshold values with lower threshold corresponding to the breakdown (resorption) of bone tissue under insufficient level of loads and upper threshold triggering growth of additional tissue under excessive loading (Frost, 2001). From the microstructural point of view it was found that microcrystals of hydroxyapatite in healthy bone tissue are oriented in preferential direction and in bone subject to SSE this orientation is degraded resulting in reduced BMD (Mie et al., 2020).

Selection of fixation plate with optimal stiffness is a compromise problem since, on the one hand, too low stiffness will result in unstable positioning of bone fragments with risk of malunion, but, on the other hand, excessively high stiffness provokes SSE with associated risk of osteopenia and secondary fractures. Ideally plate's stiffness should adapt to the changes of bone biomechanical properties during healing process: in the terminal stages of healing stiffness can be reduced, because fusion of bone fragments precludes their relative displacements. Gradual reduction of plate's stiffness during fracture healing is inherent property of plates made of biodegradable materials like magnesium or bioresorbable polymers (Sheikh et al., 2015; Gaynetdinova et al., 2018). However, rate of material degradation should be matched to the speed of bone healing and, since the latter factor is somewhat unpredictable (patient-specific), application of biodegradable plates does not guarantee optimal outcomes of treatment. So called "dynamizable plates" provide possibility of externally-controlled stepwise reduction (switching) in plate's stiffness upon formation of sufficiently reliable fusion between bone fragments (Dichio et al., 2020). Switching time is selected depending on the speed of bone healing and for this reason dynamizable plates enable patient-specific treatment protocol: however, this advantage is achieved at the expense of structural complexity.

Since plate's stiffness depends both on material properties and geometric shape and dimensions of the plate, possibility of variations in geometric shape provides additional flexibility in the design of plates, especially when material choice is limited due to biomedical or technological constraints. In structural design there are two main approaches to the creation of optimally-shaped objects: shape optimization and topology optimization (TO). In contrast to shape optimization TO not only varies shapes of existing object boundaries, but also allows for creation of new internal boundaries (“holes”) or vanishing of existing internal boundaries or, in other words, allows for the changes in object’s topology (Bendsøe & Sigmund, 2003). Optimality of the final topology is qualitatively evaluated in terms of the certain objective function related to the performance efficiency of the object and taking maximum or minimum value for the optimal topology. Frequently used objective functions in mechanical engineering are stiffness (under certain kind of external load, e.g. extensional or flexural load) and total energy of elastic deformation (TEED). These objective functions are equivalent and design with maximum stiffness will have minimum value of TEED. From the practical point of view TO enables design of structures with reduced weight (in comparison to initial non-optimized design) with high performance efficiency, e.g. high stiffness. Successful application of TO is closely related to modern advances in precision numerically-controlled methods of additive manufacturing capable for production of objects with arbitrarily complex shapes.

Today TO is widely used in design of medical implants including osteosynthesis plates (Wu et al., 2021). Existing TO methods generally rely on finite element meshing of design domain and include method of evolutionary structural optimization (ESO), method of homogenization and density-based methods. ESO is based in iterative removal of “insufficiently used” finite elements from design domain: for TEED objective function elements are classified as insufficiently used if they have low mechanical stresses (Xie & Steven, 1997). Method of homogenization is used for multiphase composite materials, e.g. laminates and cellular materials. In this method shape of the object remains unchanged and optimization is achieved by spatial variation of effective (volume-averaged or homogenized) properties of composite depending on phase content and design of unit cell (for cellular materials). Density-based methods introduce dimensionless pseudodensity variable θ assigned to each finite element in design domain and taking values from θ = 0 (absence of material) to θ = 1 (solid material). Optimized design is described in terms of associated pseudodensity distribution. More detailed description of optimization method used in the present study will be given in Material and Methods section.

3. Material and Methods:

TO using density method was implemented for 2D and 3D problems of osteosynthesis plates design using Comsol Multiphysics software. Design domains (initial non-optimized designs) are presented in figure 1.

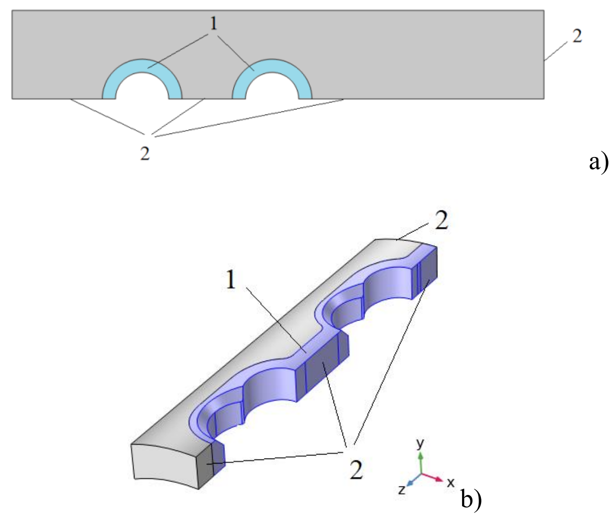

Figure 1 – Design domains for 2D (a) and 3D (b) problems

Geometric symmetry of the plates was accounted by considering incomplete quarter-models with symmetry boundary conditions (roller constraints) applied to the midlines/midplanes 2. Overall dimensions were 180 × 30 × 3 mm for 2D model and 94 × 13.5 × 3.5 mm for 3D model (for complete models). To preserve shape, dimensions and positions of screw openings during optimization they were surrounded with the areas of prescribed material density (APMDs) θ = 1 (denoted as 1 in figure 1). Modelling was implemented for 21S titanium alloy (metastable β titanium alloy with composition Ti–15Mo–3Nb–3Al–0.2Si in weight percent). Alloys of this kind are prospective for applications in biomedical implants due to their biocompatibility, high strength and low elastic modulus: the latter property is advantageous for reduction of stiffness and SSE (Pesode & Barve, 2023; Niinomi & Nakai, 2011). Screw openings were loaded with 35 N tensile load corresponding to compressive load of the same value applied to the bone. In 3D model zero-gap contact between curved bottom surface of the plate and bone surface was modeled using additional boundary condition $\mathbf{u}\cdot\mathbf{n} = 0$, where **u** is displacement vector, **n** is surface normal. TEED objective function subject to minimization was used. Prescribed reduction of weight (PRW) no less than 50 % relative to initial design was used as optimization constraint. To prove convergence of analysis design domain in 2D model was meshed with free triangular mesh with maximum element size varying from 3/2 mm (coarse mesh) to 3/16 mm (fine mesh) with two intermediate refinement steps (3/4 and 3/8 mm). 3D model was meshed using free tetrahedral mesh with 0.25 mm maximum element size.

Optimization was performed using SIMP method (Solid Isotropic Material with Penalization for intermediate densities) belonging to the density-based methods (Bendsøe & Sigmund, 1999). In this method pseudodensity takes values from $\theta_{\min} > 0$ (preset value in Comsol is 10^{-3}) to $\theta_{\max} = 1$ and elastic modulus is expressed as

$$E = E_{\min} + (E_0 - E_{\min})\cdot\theta^p, \quad (1)$$

where $p > 1$ is integer penalization exponent, E_0 is elastic modulus of solid material, $E_{\min}$ is elastic modulus for $\theta = \theta_{\min}$.

Penalization of intermediate densities ensures that most of the elements in final topology will have pseudodensity $\theta = \theta_{\min}$ (white elements) or $\theta = 1$ (black elements). Ideal solution of TO problem should contain only these two kinds of elements, because elements with intermediate values of pseudodensity (grayscale elements) cannot be realized during manufacturing from homogeneous material, where each voxel of the object have only two possible states: presence or absence of material. Grayscale elements can be realized only for composite materials with structurally/compositionally controlled effective properties.

For suppression of numerical instabilities (mesh dependency of solution and checkerboard patterns) Comsol Multiphysics uses density filtering by means of low-pass Helmholtz filter of spatial frequencies (Lazarov & Sigmund, 2011). Filter radius r_f is inversely proportional to the spatial cut-off frequency and should be no less than maximum element size $e_{\max}$ in the mesh: in present study we used condition $r_f = 2e_{\max}$.

Additional suppression of grayscale elements is achieved using hyperbolic tangent projection filter which can be considered as regularized Heaviside step function with smoothed transition between the ranges of zero and unit values (Guest et al., 2011). Projection filter is described using parameter β: increase of β results in more steep transition and more efficient suppression of intermediate values of pseudodensity.

In summary Comsol Multiphysics has 4 density variables (listed in the order of their computation): θ_c – initial density (before penalization, filtering and projection), θ_f – filtered density, θ – projected density, θ_p – penalized density. Speed of convergence and quality of solution (number of grayscale elements) are controlled using two parameters: penalization exponent p and projection filter slope β. Increase of these parameters produces solutions of better quality, but slows down computation process. Well-known solution of this problem consists in so called adaptive continuation (Guest et al., 2011): initial low-quality solution is obtained for low values of p and β and then used as non-trivial initial approximation for subsequent step with higher values of p and β producing solution of better quality – this process can be iteratively repeated. In present study we used 4 iterations with the following values of p and β: (1, 2), (2, 4), (3, 6), (4, 8).

4. Results and Discussion:

Convergence of solution for 2D problem is illustrated by figure 2.

During gradual increase in the number of finite elements (corresponding to reduction of their maximum size from 3/2 to 3/16 mm) TEED approaches stable value and final topology becomes very close to binary (black and white) design with minimum number of grayscale elements.

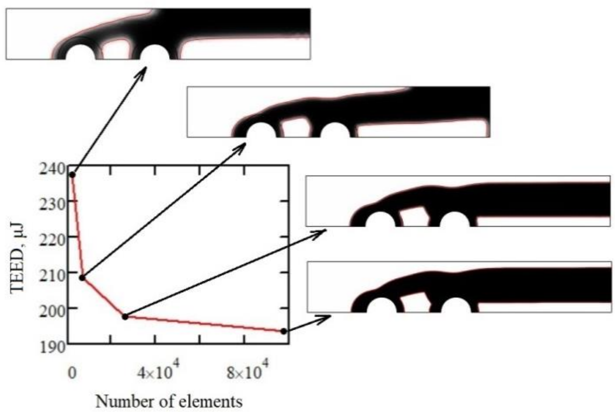

Figure 2 – Results of convergence study for 2D model

Variations in the shape of optimized plates are negligibly small in the 4th step relative to the 3rd one and more evident if compare final result with preceding steps with coarser mesh. Overall shape of optimized plate is in good agreement with results of similar studies (Gaynetdinova et al., 2018; Gogarty & Pasini, 2015).

To perform static analysis of generated topology we extracted isolines of penalized density $\theta_p = 0.2$ as discrete sets of points and used them for creation of continuous interpolation curves describing boundaries of the plate with optimized design. Optimized plate has shown 36 % reduction in longitudinal stiffness relative to initial design and, as a result, will produce less pronounced SSE. On the other hand, optimized design has maximum stiffness for the given value of weight. Prototypes of the plates can be easily manufactured using laser cutting or wire electrical discharge machining (EDM). Wire EDM has some advantages over laser cutting since it produces precise cuts with high surface quality and generates no heat affected zone. However, due to technological limitations we used laser cutting with subsequent plasma electrolytic etching to improve surface quality. As-cut sample is shown in figure 3.

Figure 3 – Laser-cut prototype of the plate

Optimized plate shows around 20 % increase in maximum von Mises stress, however it demonstrates more uniform overall distribution of stresses (figure 4, for better visual perception stresses are shown on logarithmic scale).

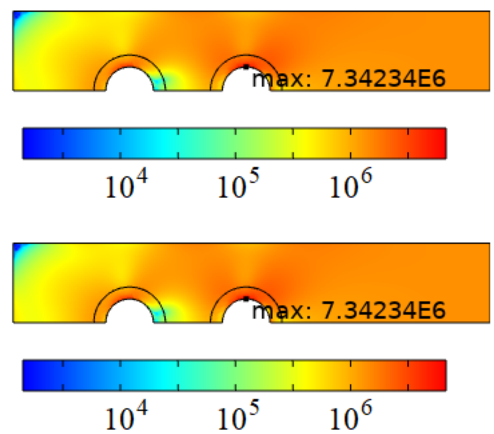

Figure 4 – Distribution of stresses (Pa) in initial (a) and optimized (b) designs of the plate

Effect of PRW constraint on topology and stiffness of optimized plates is illustrated in figure 5.

As in the case of ESO, optimization firstly removes least stressed regions of the plate situated at the corners and near distal (relative to the transverse midline) openings (blue and cyan regions in figure 4a). By varying PRW value one can produce designs with stiffness reduced up to 84 % relative to initial design. It should be noted that real reduction of weight will be somewhat lower than its expected value given by PRW, e.g. 47.3 % at PRW = 50 % and 85 % at PRW = 90 %. The reason is that real design is produced from simulated grayscale topology using thresholding (with condition $\theta_p \geq 0.2$) and some low-density “grey” elements are interpreted during this procedure as solid material.

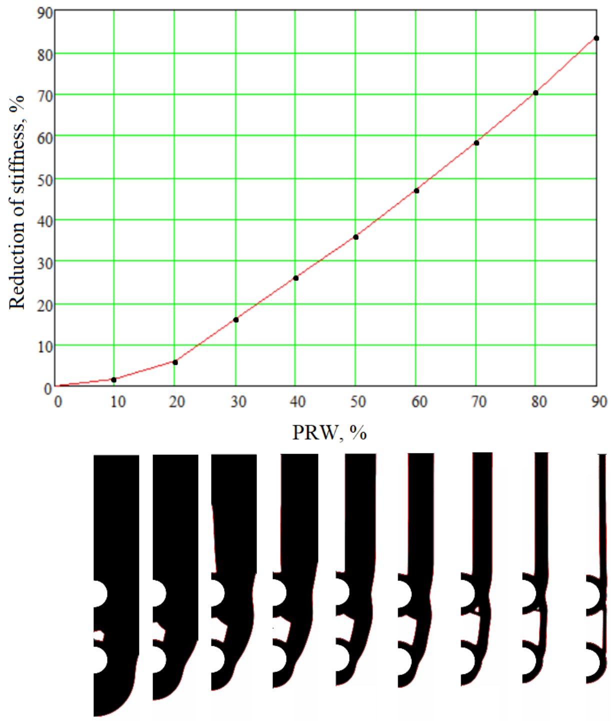

Figure 5 – Topology and stiffness of the plates as a function of PRW constraint

Optimization results for 3D model will be presented in the future studies. However, in conclusion we would like to highlight some fundamental differences in methodology of 3D TO.

The main drawback of 2D model is simplified representation of screw openings. Simple cylindrical openings are rarely used, e.g. locking compression plates are manufactured with complexly-shaped combined openings (figure 1b) providing possibility to use two kinds of screws: compression screws with spherical heads ensuring compression of bone fragments and locking screws with threaded conical heads ensuring angular stability of the plate in the case of its implantation with a gap relative to the bone surface (Cronier et al., 2010) (implantation of this kind preserves normal vascularization of periosteum; thread is removed in finite element model to avoid excessively dense meshing). Complex shape of screw openings dictates the need for more complex (in comparison with 2D model) geometry of APMD (denoted as 1 in figure 1b). In 2D model each screw opening is surrounded with its own APMD and individual APMDs are not connected to each other. In 3D model utilization of separated APMDs resulted in the loss of connectivity in the final topology: design domain was broken down into several subdomains not connected to each other. To avoid this problem APMDs should be “bridged” together in 3D model with formation of single APMD: however, there are different possible topologies of such bridging and their effect on final solution should be additionally studied.

Another important difference is related to verification of TO results. For both 2D and 3D models verification is performed by means of static analysis of optimized design. However, we have to use different approaches to transform distribution of pseudodensity produced by TO into the model appropriate for static analysis. As it was described earlier, for 2D model this task is implemented by extracting isolines of penalized material density θ_p. For 3D model this approach was found to be unfeasible, because irregular shape (particularly, lack of smoothness) of extracted isosurfaces resulted in hard-to-fix problems: we tried to extract isosurfaces as point clouds with their subsequent transformation into interpolation surfaces and represent isosurfaces as STL meshes, but both methods were unsuccessful. For this reason we came to the idea of performing static analysis on the same mesh as TO, but with spatially-dependent material properties (elastic modulus and density). To describe this dependence we represented distribution of θ_p obtained from solution of TO problem as 3D interpolation function and assigned material properties depending on the values of this function: similarly to equation (1) low values of θ_p were mapped into the values of elastic modulus and density essentially smaller than corresponding properties of the solid material.

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