METHODS

Mathematical Model of Little Invasive Interventions on the Hollow Organs Using Traditional and Shape Memory Ni-Ti-Based Biocompatible Superelastic Materials

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Comparative analysis of the mode of deformation of hollow organs (extrahepatic bile ducts at the site of stricture) was carried out by the finite elements method during interventions in the lumen using stone extraction Dormia basket made of stainless steel and NiTi. Geometrical and physical models of the ducts and basket were created, strain and deformation fields in the choledochal walls were determined, criteria of traumaticity and medical technological requirements to the material and geometry of lithoextractors were formulated.

Key Words: *simulation; Dormia basket; bile duct; biocompatibility; little invasive methods*

Little-invasive therapeutic and diagnostic interventions on the organs became possible due to integration and cooperation of various disciplines and branches of medicine, for example, technology of biomedical materials, physiology, and computer simulation.

According to statistical data, one-quarter of the world population suffer from biliary system diseases [3]. Irrespective of the tasks facing the surgeon (draining, cleansing of the bile ducts from bile sludge, or lithoextraction for choledocholithiasis), the treatment efficiency depends on the material and geometry of the instruments and devices. The most hazardous complications of interventions on the extrahepatic bile ducts by means of Dormia basket are mechanical injuries to the inner surface and the walls of the ducts by the working parts of the baskets. The percentage of relapses is particularly high in concomitant cholangitis and strictures (pathological stenosis of the bile ducts, resultant from inflammatory processes or previous diagnostic or surgical interventions). Intricate topology and geometrical heterogeneity of the bile tree increase the risk of complications in interventions in the lumen and create additional prerequisites for wounding the ductal walls. The diameter of biliary system ducts in various compartments can be very small even normally (for example, the terminal part of the choledochus). The gallbladder neck (Hartman pouch) and entry into the cystic duct represent a narrow segment and a funnel-shaped area. Reduction of the duct lumen deteriorates its patency and is fraught with not only disorders in bile discharge, but also with their iatrogenic damage during interventions in the lumen. One of difficult situations is when the Dormia probe is inserted via the fistula to the choledochus and moved up or down the duct. In some cases the loop has to be brought behind a concrement completely or almost completely blocking the duct, in order to capture the stone "encrusted" in the duct wall, *etc.* Safety and minimization of traumatism in instrumental sanitation of the bile ducts is a pressing clinical prob-

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lem, essential for subsequent complications of the immediate and remote postoperative period.

We studied mechanical characteristics of the lithoextractor material and choledochal wall *in vitro* and carried out estimations of mode of deformation (MD) during interventions in the lumen by the finite elements (FE) method. The histology was studied and morphometry of the gallbladder wall, cystic duct, and proximal portion of the choledochus were carried out on autopsy material. The aim of this work was to determine the optimal parameters of the lithoextractor working piece in order to minimize the incidence and severity of iatrogenic injuries to extrahepatic bile ducts.

MATERIALS AND METHODS

Khachin's loop [10] with a branch net thickened at the distal end was considered in the study as the Dormia basket. The basket consisted of thin metal wires connected to each other in a special way: rigidly bound to each other at the ends of the branch and connected in the torsion zone, being moved as a whole unit.

Stainless steel (traditional material) and titanium nickelide (nitinol, NiTi) as the materials for Dormia baskets were analyzed. NiTi is characterized by high corrosion resistance, biological inertness, which was demonstrated in numerous experiments on animals [2], and elasticity, its histeresis is close to that of living tissues in the loading/unloading diagram, and this material is capable of up to 10% reversible deformation [5].

Physical mechanical characteristics of the structural components of the model were studied for creating the physical model and obtaining reliable results. Elastic characteristics of NiTi were previously studied in detail on monocrystals [9]. Mechanical characteristics of the choledochal wall were studied *in vitro* by the infusion method. The measurements were carried out at room temperature in saline (pH 7) without Ca^{2+} ions and simulating the biological fluids of the body. Excessive transmural pressure in the duct segments was evaluated by the liquid column height. The length and external diameter of the segment were measured at different pressure for estimating the deformations. The thickness of the wall was calculated by the formula [1], assuming that the wall material was homogeneous and incompressible [11]. The initial thickness at 0 kPa was measured before trials. The tension in the longitudinal and annular direction was calculated by the Laplace equation for thin-wall cylindrical membrane [7].

Common bile ducts (autopsy material from 8 men and women aged 40-60 years without hepatic and choledochal diseases; time between death and autopsy 12-24 h) were examined. Segments were analyzed after histological trials. Autopsy material was fixed in 5% formalin and paraffin blocks were prepared, from which 5-μ sections were sliced on a Leica RM 2135M rotor microtome and stained by hematoxylin and eosin; collagen fibers were post-stained by Van Gieson's method. Ready histological preparations were studied under Leitz BIOMED binocular microscope and photographed.

The main tensions and deformations were evaluated by the FE analysis [6] using ANSYS software [4].

RESULTS

Histological studies revealed no pathological changes in the ductal wall.

Based on the results of mechanical trials of the choledochal wall, the strain-deformation curves for the longitudinal and annular directions were plotted. The curves were J-shaped, which was characteristic of large blood vessels [7]. Anisotropy (orthotropy) of physical mechanical properties of the choledochal wall was established. The differential elastic moduli in both directions were tabulated and dot-by-dot introduced when specifying the properties of materials at the pre-processor stage of analysis.

Geometrical and physical FE models were developed for numerical analysis of MD. The final working model was lamellar (periductal tissues, duct, basket). Direct external thick-wall coaxial tube simulated soft tissues enveloping the choledochus, with the mean effective mechanical properties of the hepatobiliary ligament (Young's elasticity modulus E=1-5 MPa, Poisson's coefficient m=0.49). Cone-shaped narrowing thin-wall tube of alternating transverse section simulated the choledochus fragment with incomplete stricture. The third component was the three-branch netted basket twining at the tip. Both tubes (periductal tissue and choledochus) simulated three-dimensional solid with elements; when determining the threshold conditions, their ends were rigidly fixed at the contour (point fixation did not give the desired results). The model was designed symmetrically; the number of nodes in the finite elements network reconstruction was 33,036, the dimension of the problem was 99,108 (hexahedres as the FE type). The actual effect of tissues adjacent to the choledochus was also replaced by application of "manual" fixed exercise, constant for the entire surface of the duct. In fact, the mathematical 3D basket model was constructed by the fragment-linear spline by means of segmented exchange of geometry with precise design of the construction. Surface-surface type contact elements were used to simulate the interactions between the branches (rods) of the basket and the ductal wall. Introduction of the basket from the first contact until complete penetration into the duct was realized by discrete predetermination of transpositions at the ends by means of a stepwise function f(t)=0.0007t, where t=1, 2, ..., 30. Hence, the basket moved "quazisatically" (by 0.7-mm steps). The geometrical heterogeneity used in the choledochus model made it possible to calculate the contact pressures and for all diameters of the duct and at all stages of the basket passage (beginning of introduction, passage of stricture, and position in the narrow part). Tension and deformation in the duct wall were calculated [8]. The factors that had to be taken into consideration at the stage of the model mastering and practical realization were the significant nonlinear pattern of the task, computing technique resources during triggering the estimation, and significant discrepancy between the characteristic sizes of the branches' elements and morphometrical parameters of the choledochus (diameter and wall thickness), which were essential for the fitness of the method and accuracy of results (error).

At all stages of basket introduction the maximum strain and deformation values were recorded for the zones of basket branches with the duct wall. In accordance with the selected criteria, constructions from materials with low elasticity (NiTi) exhibited the minimum traumaticity. Working pieces of NiTi constructions dilate the choledochal wall tissues to a lesser extent. Inserted into stricture areas, into narrow and twisted ducts, they better copied the relief and acquired the shape of the ducts. When removing the concrements from blocked ducts, the loops gently deformed the organ and penetrated behind the concrement (due to the olive guide at the tip). Due to the multi-branch design, the area of contact with the ductal surface could be increased and the contact pressure reduced. It was clinically confirmed that thickening of the branch net at the distal end of the probe improved the efficiency of capture and facilitated traction of the concrement [10].

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