Mobile endoprosthesis of radial head

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1. Introduction
Fractures of radial head constitute from 1.7 to 5.4% of all the fractures of human joints [1]. These fractures are often accompanied by extensive soft tissue injuries also in the vicinity of wrist. In such cases nailing of bone chips does not yield good effects. Resection of radial head or its replacement with an endoprosthesis is a method of radial head multi-chip fractures treatment. The radial head resection often causes loss of stability in elbow joint and wrist ache related to the radius migration in the direction of the elbow joint. The alternative method of treatment is endoprosthesis implantation. A correctly designed and chosen endoprosthesis allow the patient to quickly return to health and maintain good functionality of the limb.

2. Methods
In the paper estimation of functionality of a new radial head endoprosthesis construction is presented. The distinctive feature of this construction is the mobile articulated joint between the head and the stem. This joint enables the endoprosthesis head to adjust its position to the other joint surfaces of elbow. Displacement of the head in relation to the stem is limited by the stem collar. Two-part endoprosthesis construction has a short stem, which makes the surgery easier. At first, the stem is implanted in medullar cavity of radius, then the head is assembled. This procedure makes it possible to complete it in small operation area. The endoprosthesis head shape is designed such that it fit the natural elbow joint surfaces [2]. The frontal area of endoprosthesis mates with humeral bone joint surface while the side area mates with the articulation surface of elbow. The head shape and the aforementioned articulated connection with the stem ensure correct arrangement and adjustment of the co-acting endoprosthesis head surface and that of elbow joint bones. Furthermore, endoprosthesis stem has a limiting collar. This collar allows for stable fixation of the stem in the narrow cavity. The articulated connection allows for free head rotation in relation to stem axis and simultaneous deflection in range ±15° [3]. The size of the head deflection in relation to the stem was determined on the basis of the analysis of the radial head geometrical parameters. The radial head location changes while pronation and supination movements are realised [4,5]. In order to make the selection of the geometrically correct endoprosthesis for the concrete patient easier documentation of endoprosthesis type-series was made. The documentation takes into account the three basic parameters, i.e. the head diameter and its height, the neck length and the stem length [7]. The constructional features of the new radial head solution are also the object of a patent reservation [6]. The endoprosthesis prototype was studied in two-stage researches. In the first step numerical simulations by means of finite element method were carried out. The simulations allow one to define tentatively the construction correctness in regard to its strength. In the second step assessment of the articulated joint between the head and the stem was carried out.

3. Results
The researches were directed to assessment of the endoprosthesis functionality in the conditions similar to natural ones in joint. The researches included also determination of the force necessary to connect and separate endoprosthesis components. These researches were done on the strength machine. In order to complete the force determination a special instrument-handle, which made it possible to arrange the endoprosthesis in the machine at the required angle (0°, 5°, 10°, 15°) was designed. Determination of the force value was done in tensile test. In the next step durability tests of the endoprosthesis construction were carried out on the elbow joint simulator [8][9]. The endoprosthesis functionality assessment came down to observation of the construction stability under the load of its characteristic components during the movements of the joint, i.e. flexion, extension, pronation and supination. The range of flexion and extension movements equals 135° and is realized by swing motion of the simulator horizontal engine handle. The supination movement to 70° and pronation movement to 50° was realized by rotational movement of the simulator vertical engine handle. The work of both driving system, i.e. vertical and horizontal, could be independent or synchronised. The endoprosthesis was fixed in special handles placed on the extension of the engine axis.
The research took place in physiologic saline, which is 0.9% solution of salt in distilled water. The endoprosthesis underwent cyclic movement composed from bending movement and rotation under the load of 250N. The endoprosthesis stem was fixed in handle which was extension of the vertical engine axis and made rotation movements in the range ±45°. The endoprosthesis head was sliding on teflon insert in lower handle which was extension of the horizontal engine axis and realising the swing movement in the range ± 15°. By measuring the distance between the centre of the polyethylene insert spherical surface and the frontal surface of the endoprosthesis head the degree of the components wear was determined. In the researches the series of prototypes was tested, which gave the basis to safe clinical application.

4. Discussion

The endoprosthesis implantation is very effective method of prototypes verification. The endoprosthesis presented in the paper, considering construction features, gave positive prognosis in regard to correct functionality of the endoprosthesis itself and the whole limb. The mechanical and durability researches made it possible to pre-operatively verify the construction. The results will be used as introduction to comparative research with other endoprostheses of the type available on the market. This will allow one to indicate its higher functional quality. The research of the force connecting and separating the articulated joint of the endoprosthesis show that the value depends on deflection angle. The highest value of the force corresponds to the head deflection. This leads to the conclusion that separation of the head and the stem will not occur during the joint functionality. Important conclusions were also drawn from durability researches carried out on the elbow joint simulator. The realised number of cycles, which exceeded million, gives a notion of long-term functioning of the endoprosthesis in the joint. It may be concluded that the articulated joint wear in this scope does not have any negative influence on further endoprosthesis functioning, i.e. stability and durability of the articulated joint is maintained.

In order to acquire the licence for national production researches on the new construction functionality have to be carried out according to the requirements of the EU standards.

References