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Original scientific paper

TOWARDS PATIENT SPECIFIC PLATE IMPLANTS FOR THE HUMAN LONG BONES: A DISTAL HUMERUS EXAMPLE

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Abstract. *Plate implants are the most used internal fixators for the surgical treatments of the bone fractures. In clinical cases where there is a requirement to use reconstruction plates, and/or to stabilize the fracture, adaptation of plate shape (e.g. bending) to the patient anatomy is required, and it is usually done during the surgery. In order to eliminate the need for intra-operative bending of plates, precontoured plates can be used. These are patient specific implants whose shape and geometry is adapted to the anatomy and morphology of the specific patient. In order to create a patient specific 3D model of the plate implant, the bone model acquired through medical imaging (e.g. Computed Tomography - CT) is commonly used. By the application of various CAD techniques, the volume model of specific plate implant can be created, and used for the production of the plate, by conventional or additive manufacturing technologies. In this paper the authors present a new approach to the creation of a 3D parametric model of the patient specific plate implant for distal humerus. By using such model the surgeon can perform preoperative planning and adapt shape of plate to the specific patient before the surgery, and in this way he can improve pre, intra and post-operative processes.*

Key Words: *CAD, Orthopedic, Fixator, Plate, Parametric models, Method of Anatomical Features*

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1. INTRODUCTION

In the field of orthopedic surgery there is a requirement to provide the best possible medical treatment for the patient with a bone fracture. For the treatment of bone fractures the surgeons apply techniques of internal and external fixation. External fixation is a surgical technique used for stabilization of bone fragments with the fixator positioned outside of the human body (only pins and screws are implanted inside the body) [1]. The alignment of the external fixator can be adjusted externally to provide an optimal position of the bone and bone fragments during the recovery process. Internal fixation presumes the use of osteofixation material (screws, pins, plate implants) inside the human body in order to stabilize the bone fracture [2-5]. Both internal and external fixation can be used for the healing of the bone fracture, but internal fixation is preferable because it provides better functional recovery of the bone [2].

Plate implants are the most used internal fixators for surgical treatments of the bone fractures. They are made in various sizes and shapes in order to be used for different patients [4]. The application of such implants for the treatment of the unique patient bone may initiate a problem because of differences in size and shape of the bone and the plate implant. In such cases it is hard to find proper position of the plate; the patient's treatment may be hampered due to an inadequate transfer of load during the bone healing process, etc. This problem can be reduced by the application of so called Patient Specific Plate Implants (PSPIs). The geometry and shape of PSPIs are adapted to the anatomy and morphology of the bone belonging to the specific patient [5-8]. Application of PSPIs has a positive effect on patients, but, on the other hand, it requires more time for preoperative planning and their manufacturing. Therefore, PSPIs are used in the cases where the application of predefined implants can lead to both intra-operative and post-operative complications.

Distal humerus fractures are common fractures of the human arm (elbow). It is of great importance to properly stabilize the elbow while the patient is in the recovery process [9, 10]. For this purpose precontured plates are used. If the quality of the bone is poor (osteoporotic bone), then angular stable plates are used [10]. In the cases when standard plates are used for fixation of the distal humerus fractures, the plate must be adapted to the shape of the patient bone (bending of the plate during the surgery) [10, 11].

In order to improve the pre-, intra-, and post-operative procedures in the treatment of the distal humerus fractures the authors propose application of the PSPI created by the new technique presented in this paper. This technique enables the creation of the geometrical model of the PSPI whose contact surface with the bone is adapted to the bone's geometry and morphology. For this purpose, a parametric model of the PSPI is created by using one clinical case as an example; hence it should be considered as a prototype model, which will be tested on more samples, and possibly improved in future research. The parametric model is a model whose geometry can be modified by changing the value of parameters (specific dimensions) while its topology remains unchanged. This model is created by the application of the Method of Anatomical Features (MAF) which enables the creation of fully geometrically defined anatomical surfaces of the human bones [6-7]. This model can be used as the basis model for the production of the PSPI by applying additive or conventional manufacturing technologies.

It should be noted that the main intention of this research is not to create a plate parametric model which can be fully applicable to all human bones or part of the bones (or all bones of the same type). That is practically impossible but if the created PSPI model can reduce the surgeon's effort to customize the plate during surgery and to shorten the time of the intervention, that would bring a great benefit to the clinical practice, and, of course, to the patient.

This paper is structured as follows. In the second section of the paper, a survey of the internal fixation and fixation components (osteofixation material) is presented. The technique for the creation of the PSPIS geometrical model for the fixation of distal humerus fractures is presented in the next section of the paper. Finally, conclusion is presented together with the prospects for future work.

2. BASIC PRINCIPLES OF INTERNAL FIXATION

Internal fixation must follow three main principles: it must enable the movement of muscles and joints in the area of fracture; it must provide complete restoration of the bone; and it must enable a direct union of the bone fragments without visible deformation in other areas of tissue (like forming the visible callus) [12]. The main tasks for the internal fixation are to enable stability to the bone and surrounding tissue, to maintain blood supply to the bone, and finally to prevent possible fracture diseases like infection in the area of trauma [12]. In the process of internal fixation the surgeon can invoke two patterns of stability, which will influence the type of bone healing that will occur: absolute stability (results in direct bone healing), and relative stability (results in a secondary or indirect bone union). Absolute stability means that there is no movement between bone fragments, and relative stability means that the bone fragments can create motion during their union with the main bone or with each other [13].

In order to enable proper healing of the bone, the surgeons use various mechanical components which provide mechanical and functional stability to the bone during recovery process. The main components which are used for internal fixations are: wires, pins, screws, which are defined in [12-20] and plates [20- 31].

2.1 Plates

In today's medicine various types of implants are used for the fixation of human bones fractures [21]. The most common ones are plates and their variations. The metal plates have been in use for more than one hundred years. Among the first plates were compression plates which use various designs and external devices to enable compression of bone fragments [21]. Compression plates with oval holes introduced the Dynamic Compression Plates (DCP) [22]. Oval holes were used in order to provide interfragmentary compression during screw tightening. The advantages of the DCP included a low incidence of malunion, stable internal fixation, and no need for external immobilization, thus allowing immediate movement of neighboring joints [21, 22]. To provide adequate stability and to enable functional requirements of the bone, DCPs have to be mounted onto the periosteum (the tissue that lines the outer surface of all bones) and should be pressed onto the bone to achieve stability [21-24]. This requirement raises one important issue and that is cortical bone porosis at the site of placement, due to the prohibited blood supply. However, certain doubts about this problem have been reported [24, 25] relating to the usage of plates with a reduced contact area. Refracture after plate removal was another problem with DCPs. To prevent refracture it was recommended that the plate should not be removed for at least 15–18 months [21] in order to eliminate a fracture gap between bone fragments. Different studies analyzed the reasons for refracture and the conclusion was that refracture was an effect of cortical necrosis [25, 26].

The new plate design was developed in order to reduce the plate's interference with cortical perfusion and thus decrease cortical necrosis. The design was called the limited contact-dynamic compression plate (LC-DCP) [21]. LC-DCPs make less surface to surface contact with the periosteum of the bone in comparison with DCPs (about 50%). In this way the necrosis of cortical bone and the osteoporosis under the bone were reduced. Also, LC-DCP is constructed with a plate-hole symmetry, which enables dynamic compression from either side of the hole with different intensity [21]. It should be noted that some studies [26] were conducted which shows that LC-DCP does not improve blood flow to the bone, or biomechanical properties of the bone-implant assembly.

Today, nearly all of the mentioned plate implants are substituted with the plates which are capable for both locking and nonlocking functions, such are Locking Compression Plates (LCP). Nevertheless, locked plating cannot completely replace conventional plating [23]. A combination of both plating techniques is possible and should be performed when it is possible [21, 23-25]. LCPs provide better fixation and they can withstand more load compared to standard plates (DCP) [27]. In addition to the type of fixation, quality of reduction, soft-tissue handling and the characteristics of the injury, the patient's general health status also has significant influence on the treatment results. DCP and LCP fixation methods are based on anatomically precontoured plates, reducing or eliminating intra-operative (in-situ) plate modification (usually bending). LCP does not require precise contouring because that is not required when locking screws are used. In such cases plate acts more like a fixator rod. However, greater distance between the plate and the bone can cause a problem [27-29]. It is important to mention that reconstruction plates which are designed with deep notches between the holes can be contoured (bend) in three planes to fit complex surfaces. Reconstruction plates are provided in straight and slightly thicker and stiffer precurved lengths. They have oval screw holes, like mentioned compression plates, and they allow potential limited compression [30].

The new objective in plates design and production is to achieve maximum stabilization with minimum damage to the blood supply during fracture healing. Also, there is a need for extremely rigid fixation during the healing of fractures, and less rigid fixation during later bone remodeling. In order to demonstrate the complexity of the elbow fractures, in Fig. 1 radiographs of 31 year old man with plate fixation are presented [31]. To meet the previously stated requirements, and to properly define plate shape and geometry [32], it is crucial to achieve maximal geometrical accuracy of the bone model. Construction of accurate 3D models of human bones is described in study [33], in which different methods for the creation of bone models are described. This is of great importance because with such bone models it is possible to achieve proper stabilization of bone and plate, enable adequate blood supply to the bone, perform pre-bending of plate, etc.

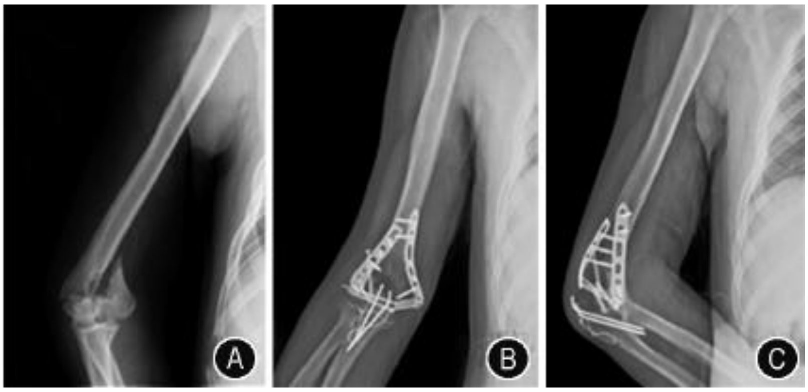

Fig. 1 Radiographs of a 31-year-old male with a right distal humeral fracture (AO type C2) who was treated by perpendicular plating. A: Pre-operative anteroposterior radiograph. Radiographs showing excellent plate location and fracture union 6 months after the primary procedure (B and C). B: Anterior-posterior radiograph. C: Lateral radiograph [31].

3. METHOD OF ANATOMICAL FEATURES (MAF)

For the CAD model creation of the distal part of the human humerus MAF was applied. MAF is a method which has already been used for the creation of geometrical models of various bones like humerus, femur and tibia. Bone models created with the application of MAF have good geometrical precision and anatomical correctness.

MAF presents a new approach to the definition of basic human bone's geometry based on the anatomical landmarks. MAF enables the creation of geometrical models of human bones, by using Referential Geometrical Entities (RGEs) defined for the each individual bone. RGEs represent the basis for the construction of bone geometry, and they are defined as the geometrical entities (points, lines, planes, axes, etc.) created in relation to the anatomical landmarks and entities. For the humerus bone, RGEs are presented in Fig. 2 and described in [34]. By using RGEs, additional 3D models of human bone can be created, like surface, volume and parametric model. In this study 3D surface model of the humerus was created and used for the definition of PSPI. The original humerus surface model was already created in previous study [34] conducted by the authors of this one, and geometrical accuracy for the purpose of presentation model was satisfactory. In order to achieve the best possible accuracy of the PSPI model, geometrical accuracy of the humerus surface model was improved in this research.

This was achieved by using additional curves with more interpolation points (points on the input digitized model acquired from CT). In Fig. 3, humerus surface model together with original model acquired from CT scan (Toshiba Acqulion 64 scanner, Slice thickness: 0.5mm, resolution: 512x512px) and previously created surface model are presented. Models are created in Dassault Systems CATIA V5 R21 software. As it can be seen from Fig. 3, a new surface model closely follows the original input model from CT.

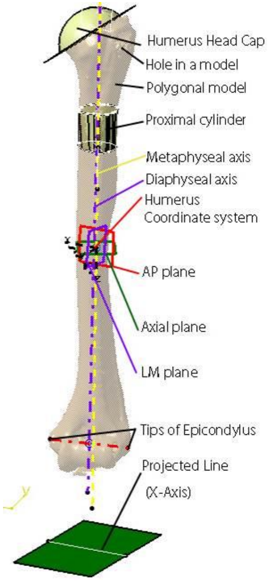

Fig. 2 RGEs defined on humerus polygonal model [34]

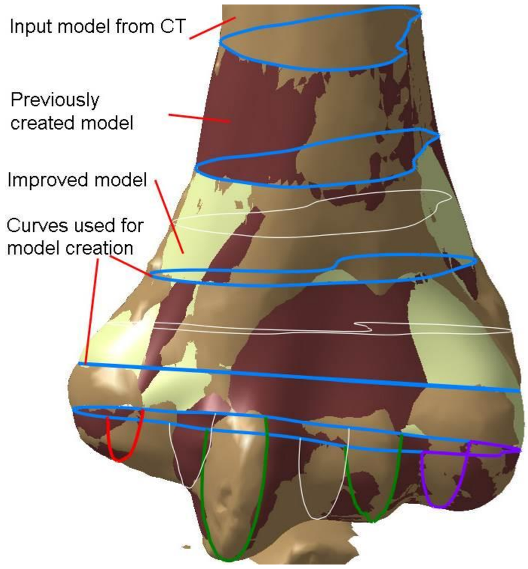

Fig. 3 Surface models and spline curves of the distal humerus (yellow – improved model; purple – previously created model; brown – input model)

Deviation analysis conducted in CATIA software, and presented in Figs. 4-6, shows that deviation range for most of the surface points of the newly created surface model is around 1mm (Fig. 6). It should be noted that, for the analysis, only the points which lie on the periosteum surface of the bone are taken into account because the input polygonal model has lot of points belonging to the inner structure of the bone (e.g. points with deviation above 3.14 mm for a newly created surface model of the distal humerus).

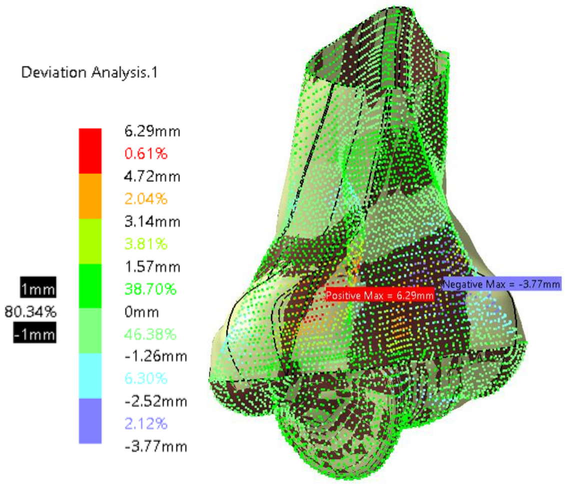

Fig. 4 Deviation analysis between created surfaces

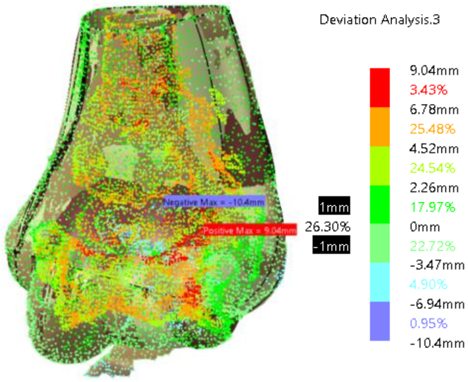

Fig. 5 Deviation analysis between input polygonal model and previously created surface

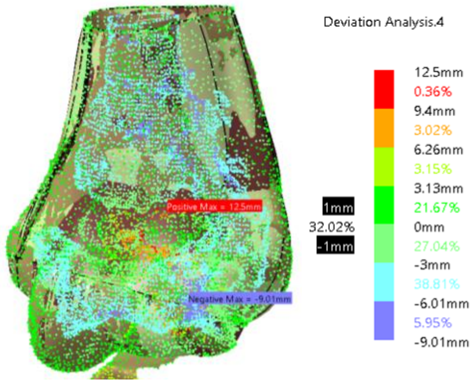

Fig. 6 Deviation analysis between input polygonal model and newly created surface

Deviation analysis between newly created surface model and previously created surface model of the distal humerus shows that in 80.34%, distance between points is below 1 mm. In regions of bone with greater curvature, maximum deviation is 6.29 mm, which confirms that additional curves are necessary for the creation of a geometrically precise model of that area.

4. Creation of Geometrical Model of Bone-Plate Contact Surface

As [10] stated, reconstruction plates are used for the fixation of the distal humerus on the lateral and medial side. On the lateral side, the plate can be placed distally onto the posterior aspect of the capitellum. On the medial side, the plate is usually bent around the epicondyle. The focus of this research was to develop and propose a new technique for the creation of one specific type of medial reconstruction plate model. The proposed technique is developed in order to improve process of plate adaptation to the bone, which is essential for the healing process of bone fracture [10].

MAF is used for the construction of plate geometrical model in CATIA. Curves which are used for the creation of a surface model of the distal humerus are used for the construction of the parametric model of the reconstruction plate, as presented in Fig. 7.

Four radiuses are defined and a medial curve was created as an auxiliary curve for surface orientation. Radiuses are defined on the spline curves which are used for the creation of the surface model of the distal humerus. Each radius defines one arc of adequate length. Arc length is a changeable parameter and it defines width of plate (it can be constant). Each arc length is defined by four corresponding arc angles. One more parameter is defined, and that is the angle of bending in the lower part of the medial plate. Bending angle regulates the distance between plate bottom surface and medial epicondyle surface of the bone. Defined radiuses (R1…R4), angles (α1…α4), medial curve and bending angle (Bending Angle) are presented in Fig. 7.

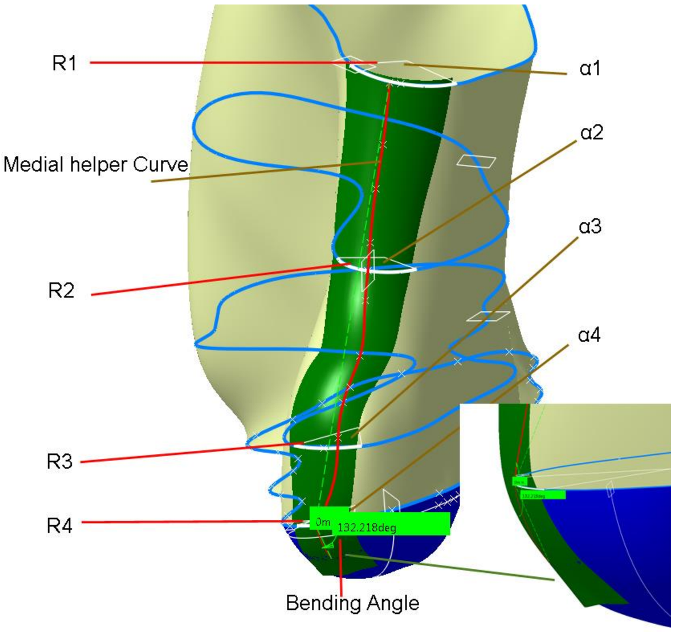

Fig. 7 Defined parameters and surface model of the bone-plate contact surface

The values of parameters for this specific patient are presented in Table 1. These values of parameters are used for the creation of the surface model of the plate contact surface. That surface is at right distance from the bone surface and the intersection with the surface of the bone is minimal and only at the end of the bended part.

Table 1 Values of parameters measured for the specific patient

R1 [mm]	R2 [mm]	R3 [mm]	R4 [mm]	Bending Angle [°]
5.3	3.7	6.1	5.7	132.2°
α1 [°]	α2 [°]	α3 [°]	α4 [°]	

Deviation analysis conducted in CATIA shape module, between surface model of the distal humerus and plate contact surface is presented in Fig. 8.

It can be concluded that maximum deviation is 0.707 mm, in outer region of the plate surface – closer to edges. Deviation range is from 0.177 to 0.707 which is pretty accurate concerning the requirement that plate contact surface should correspond to bone outer surface as maximum as possible [10].

The analysis confirms that nine parameters are enough for the definition of fixator surface shape with respect to the defined requirement.

It should be mentioned that during the real surgical intervention, the surgeon can manipulate with the plate, if there is a need for it. The surgeon can rotate, move and perform additional bending (amount of applied bending would be much smaller) in order to adapt the plate to the bone.

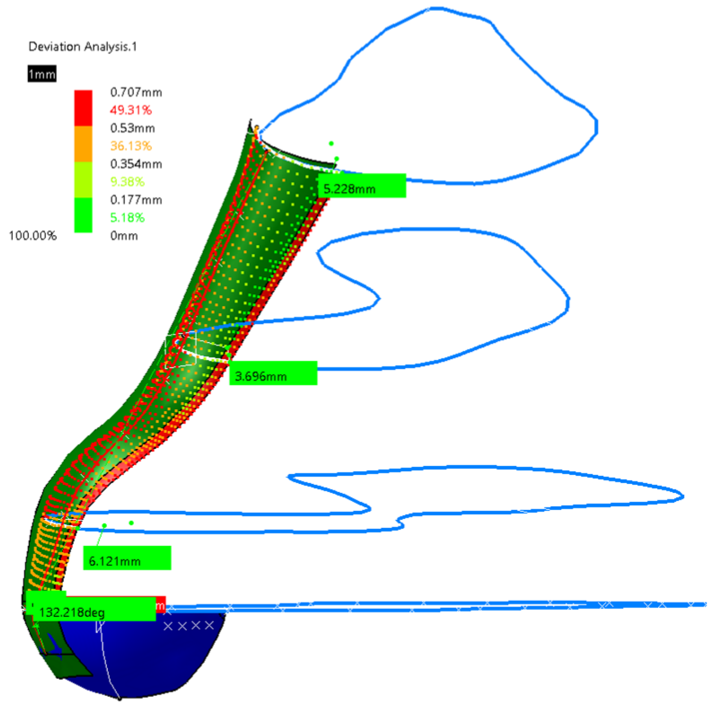

Fig. 8 Deviation analysis between plate contact surface and bone outer surface

The solid model of the reconstruction plate is created by the application of the thick surface feature in CATIA (thickness defined as 3mm), and it is presented in Fig. 9.

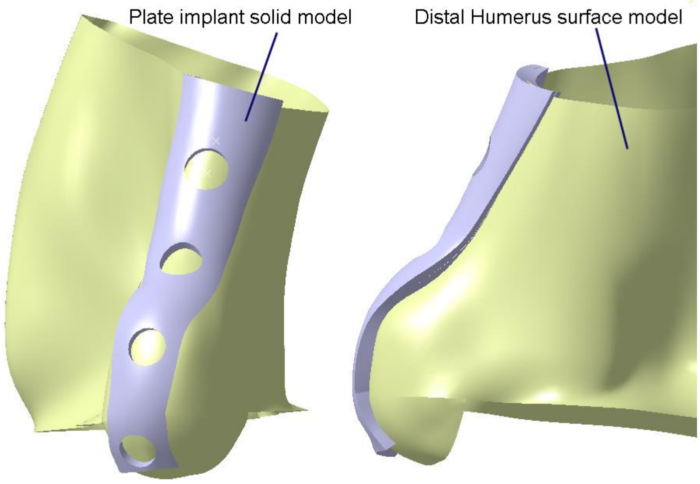

Fig. 9 Example of plate implant solid model

5. CONCLUSION

The plate implants are necessary orthopaedic equipment, and their design and ways of production should be constantly improved. This paper presents a new approach for the creation of the patient specific plate implant for distal humerus, which is based on the application of the MAF method. More precisely, it represents extensions of the aforementioned method by introducing and defining the corresponding parameters for the purpose of creating a parametric model of the plate. Pre-contouring of the plate is achieved by inserting and changing the value of the existing parameters, according to the dimensions values acquired from the 3D humerus model, while topology remains unchanged.

The possibility of plate adaptation before surgery, by using presented approach, improves preoperative processes, shortens the time of intervention as well as enables stability of the fracture and satisfies functional properties of the bone and joints. Deviation analysis between plate contact surface and bone outer surface in presented clinical case shows that plate shape is adapted to the patient specific bone in accordance with standard recommendations in clinical practise [10, 21-27]. Future work will include more bone samples in order to confirm the number and type of parameters which influence the proper construction of the contact surface between the bone and plate. Plates defined in this way can be manufactured by means of additive or conventional manufacturing technologies.

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