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Original scientific paper

REVERSE ENGINEERING OF THE MITKOVIC TYPE INTERNAL FIXATOR FOR LATERAL TIBIAL PLATEAU

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Abstract. In orthopaedic surgery it is very important to use proper fixation techniques in the treatment of various medical conditions, i.e. bone fractures or other traumas. If an internal fixation method, such as plating, is required, it is possible to use Dynamic Compression Plates (DCP) or Locking Compression Plates (LCP) and their variants. For DCP implants it is important to match the patient's bone shape with the most possible accuracy, so that the most frequent implant bending is applied in the surgery. For LCP implants it is not so important to match the patient's bone shape, but additional locking screw holes are required. To improve the geometrical accuracy and anatomical correctness of the shape of DCP and to improve the LCP geometric definition, new geometrical modelling methods for the Mitkovic type internal fixator for Lateral Tibia Plateau are developed and presented in this research. The presented results are quite promising; it can be concluded that these methods can be applied to the creation of geometrical models of internal fixator customized for the given patient or optimized for a group of patients with required geometrical accuracy and morphological correctness.

Key Words: CAD, Orthopaedic, Fixator, Parametric Models, MAF, Mitkovic

1. INTRODUCTION

Orthopaedic surgery deals with the treatment of various medical conditions related to the human musculoskeletal system, such as bone fractures, various diseases like osteoporosis or hereditary ones. For the treatment of bone fractures the orthopaedic surgeons use methods of external and internal fixation. External fixation is performed by the use of elements that are positioned outside the human body, above the skin. Internal

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fixation implies a surgical insertion of the implant in the human body, under the skin. Geometrically precise and anatomically correct 3D geometrical models of human bones are of great importance in the internal fixation implants modelling. With such models it is possible to adequately prepare surgical intervention, create geometrical models of the customized fixation elements, manufacture fixation elements, etc. In the sense of geometrical modelling, the quality of the internal fixation can be improved by the creation of more accurate geometrical models of both human bones and internal fixators. For the creation of the geometrical models of the human bones two general approaches are used. The first one is based on the generation of 3D geometrical models of bones belonging to a particular patient, on the basis of complete geometrical data gathered by the use of medical imaging methods. Such images may be obtained by the volumetric scanning methods (Computer Tomography - CT or Magnetic Resonance Imaging - MRI) or by multiple 2D scanning (xray, ultrasound) [1-4]. This approach involves the generation of 3D geometrical models using software packages which are an integral part of the medical scanner (e.g. Vitrea) [5], or by subsequent processing of medical images in medically oriented CAD programmes (e.g. Materialise Mimics) [6], or by application of various algorithms for the 3D model creation based on 2D contouring [7, 8]. One of the main disadvantages of this approach is the inability to generate the whole bone models in the cases when the medical images are incomplete or of poor quality due to osteoporosis, arthritis, or a comminuted bone [9, 10]. A complete bone model can be created, but with big approximation of its shape, which considerably reduces the quality of the model and its further application [9, 11].

The second approach to the generation of 3D geometrical models of bones or bone segments is based on the use of pre-defined predictive models of human bones [9-12]. With predictive models, the geometrical entities have been described by mathematical functions, the arguments of which are morphometric parameters or some other legible ones which can be read from medical images of a particular patient. The morphometric parameters are measurable dimensions, which can be acquired from medical images, for example CT or X-ray. Through such an approach, it is possible to generate a 3D geometrical model which best suits the physical model of the patient's bone, even in the cases when only partial data about bone shape and geometry are available [9-12]. The potential shortcomings of such an approach can be either an insufficient number of parameters or inadequately selected parameters [9, 10] or inadequately chosen prediction surfaces [11].

The common fixation technique for the internal bone fracture fixation presumes application of compression plates [13]. This group of implants can be separated on Dynamic Compression Plates (DCP) [14] and Locking Compression Plates (LCP)[15], or some type of their combination. DCP implants require a direct contact between the bone outer tissue (periosteum) and the implant. The pressure on the periosteum can lead to devitalisation of the underlying bone and it can result in plate breaking. LCP implants include screws which are locked into the plate so that they provide more stability to the assembly of the bone and the implant. There is no need for any direct contact of the bone outer surface and the implant, but it is better if the implant geometry and shape follow the bone geometry [13-16]. According to the references related to the biomechanical properties of unique plates (LCP) vs. standard plates (DCP) [17], it is concluded that the unique plates provide better fixation and they can withstand more load. In addition to the type of fixation, quality of fracture reduction, soft-tissue handling, injury characteristics

and the patient's general health status significantly influence the results. There is no evidence that the use of LCP will overcome these other factors [18].

The research in this paper is focused on the application of the newly developed Method of Anatomical Features (MAF) [6, 9, 10] for the creation of geometrically accurate and morphologically/anatomically correct models of the Mitkovic type Internal Fixator for Lateral Tibial Plateau (MIF-LTP). Three geometrical models of MIF-LTP for human tibia bone (tibia is one of bones of lower leg under the knee) are created and they are:

- Solid model of the MIF-LTP. This model is a classical CAD model which can be used for the manufacturing of the fixator by the application of classical manufacturing or by the application of the additive manufacturing processes.
- Optimal parametric model (OPM) based on the median bone geometry. This is a solid model whose dimensions can be changed according to the geometry of the specific bone. The median bone geometry is defined for the input set of bone samples, which defines the group of people for which the fixator is applicable. This means that the fixator can be used for the patient whose bone geometric characteristics fall within a group.
- Parametric Points Model (PPM) of the proximal part of the MIF-LTP which is based on the parametric surface model of the human bone developed by the application of MAF. The contact surface between the fixator and the bone is defined by the points whose values of the coordinates are defined as parametric functions [9, 10].

The geometry of all three fixator models can be adjusted in such a way that they can be used as DCP or LCP fixators. The shape is already precontoured (of course more for the PPM than for the OPM) and the holes for screws can be adjusted to achieve screw locking. It is also important to mention that both the parametric models can be transformed into solid ones by applying the generally known CAD techniques, e.g. closed surface technical feature.

The main objective of this research is to create procedures for the creation of geometrical models of the MIF-TPL which will enable orthopaedic surgeons and engineers to quickly create (manufacture) adequate physical models of the fixator for the given patient in different clinical situations.

This paper consists of four main sections. The first section contains short introduction to the MAF method. Next, MIF-LTP is described in short. In the third part of the paper, the method for the creation of the OPM of MIF-LTP is presented. The next section demonstrates the method for the creation of the PPM of the MIF-LTP. Finally, the conclusion is given including some references for the future work.

2. METHOD OF ANATOMICAL FEATURES (MAF)

Method of Anatomical Features (MAF) is developed in order to create patient specific geometrical models (polygonal, surface, and volume) and parametric (predictive) models of the human bones. The inputs for the MAF are scans of bones created by the use of medical imaging methods. These scans can be volumetric (e.g. CT) or 2D scans (e.g. X-ray). By the application of techniques and procedures created by MAF it is possible to create complete bone models even in the cases when input scans provide incomplete data

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about bone geometry, topology and anatomy, as presented in Fig. 1. For these purposes two important components of MAF are developed.

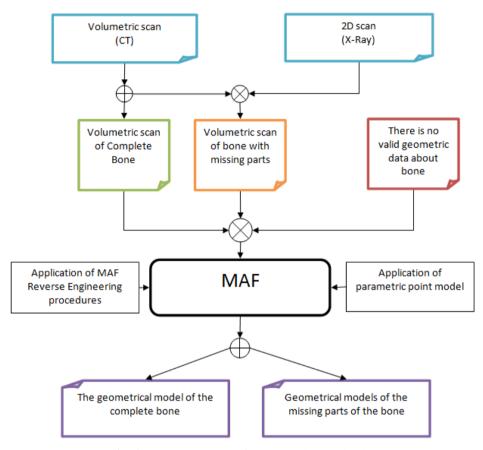


Fig. 1 The components of MAF and its application

The first component includes reverse engineering procedures which are based on the Referential Geometrical Entities (RGEs) of the human bones. The RGEs represent basic geometrical elements (points, planes, axis, etc.) and they are constructed with respect to the morphology and anatomy of the specific bone. They are described in detail in the literature [9, 10]. With these procedures it is possible to create various geometrical models of the human bones customized to the specific patient.

The second component of the MAF is a parametric model which enables creation of 3D geometrical models of the human bones even in the cases when the geometrical data about specific bone is incomplete (e.g. bone fractures or diseases, only single 2D images is available, etc.). The parametric model consists of parametric functions with arguments defined as morphometric parameters. The morphometric parameters are in most cases dimensions which can be easily acquired (measured) from medical images and they are defined individually for an explicit bone (e.g. radius of femoral head is a unique morphometric

dimension for the femur). The geometrical models of a particular bone are created by the application of acquired values in parametric functions. More detailed description of the MAF and its various applications are presented in the literature [9, 10].

3. MITKOVIC TYPE INTERNAL FIXATOR FOR LATERAL TIBIAL PLATEAU - MIF-LTP

This paper describes a method for creating a geometric model of the MIF-LTP. This fixator consists of two parts: distal and proximal. The distal part of the fixator is constructed as a cylinder so that the contact surface with the bone surface is minimized. The proximal part of the fixator is constructed as a plate whose shape is already precontoured to match that of the bone in the best possible way. The fixator can be manufactured in different sizes so that it can be applied to tibia bones of different sizes and shapes. The main characteristics (advantages) of the MIF-LTP are:

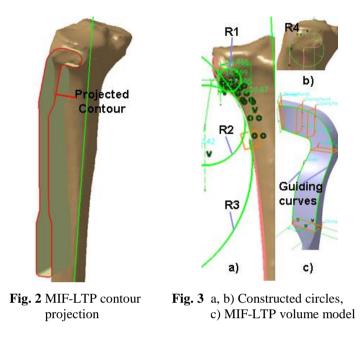
- It can be used in the treatment of different tibial fracture types: epiphyseal, metaphyseal and upper diaphyseal fractures of tibia [18],
- Minimal contact between implant and bone provides for better vascularisation of the tissue,
- Axial dynamization is possible,
- Rotational stability of the fracture is achieved,
- Application is minimally invasive,
- Hospitalization of the patient is shorter, and,
- Postoperative recovery process takes lesser time.

3.1. Optimal Parametric Model (OPM) of MIF-LTP

This paper describes a method for the creation of OPM of the MIF-LTP. Based on the fact that the bones are not shaped as typical geometrical forms and that two identical bones do not exist in reality, there is a requirement to define optimal geometry of the fixator, which can be applied on more than just one tibia. The MIF-LTP consists of two parts, distal (cylinder) and proximal (plate), whose geometrical models are made separately and then connected in one whole model. The first step in creating a geometrical model of MIF-LTP is to create the fixator's outer contour projection, perpendicular to tibial shaft tangential plane, on the tibial surface, Fig. 2. The MIF-LTP contour geometry is created on the basis of existing (real) MIF-LTP geometry and topology. It is measured on the physical sample of the fixator.

A projection curve is used to create the proximal and distal curve guidelines and limitations for the design of optimal MIF-LTP geometrical model. The process of creating proximal part guiding curves consists of two individual steps: creating the outer (lateral) and inner (medial) circles with adequate radius values on the tibial model surface. The proximal part of guiding curves is created by cutting and connecting the created circles, Fig. 3a,b. The proximal fixator part volume model is created by dragging the rectangle profile along the contour curves, Fig. 3c. The distal fixator part volume model is formed by extrusion of adequate profiles to the merging point with the proximal model. The complete fixator solid model for the specific bone (patient) is created by merging proximal and distal part models.

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3.2. Use case and results

In order to obtain optimal values of guiding curves radiuses (and thus fixing the model so that it can be applied to a number of different patients) measurements on ten different tibias (patients age 20 to 55, male and female) are performed and mean values are obtained and presented in Table 1. The values given in Table 1 are used to create a guiding curve with mean radiuses values, which is used to create a fixator volume model with optimal geometry - OPM, which is presented in Fig. 4.

Table 1 Specific guiding curves radiuses mean values for ten different tibia bones

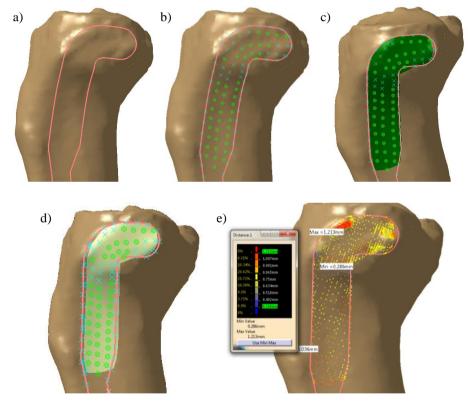
Tibia	Radius R1	Radius R2	Radius R3	Radius R4
Mean Value	15.5969	26.1637	83.0417	17.9543

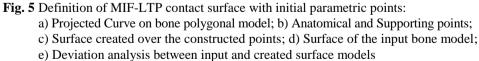


Fig. 4 OPM of MIF-LTP defined as solid geometrical model

3.2. Definition of the Parametric Points Model (PPM) of the proximal part of the MIF-LTP

PPM defines a contact surface between the inner surface of proximal MIF-LTP and the outer surface of the human proximal tibia, as a parametric model. In order to construct such surface, the input (imported) filtered polygonal model of the human tibia bone is used. The already mentioned projected boundary curve of the MIF-LTP is used as the limiting curve for the definition of the points which form the contact surface, Fig. 5a. The points are defined as anatomical and supporting [9]. The anatomical points are presented in Fig. 5b as crosses, and they closely define the geometry of anatomical surfaces (dents, crests, etc.). The supporting points are added in order to create surface of a greater geometric precision and anatomical correctness, and they are presented in Fig. 5b as circles. These points are used for the creation of the preliminary surface model of the contact surface by the use of automatic surface patch (technical feature) in CATIA. This surface model is presented in Fig. 5c.





3.3. Geometrical accuracy of the created model

To test the accuracy of the created surface, a deviation analysis is performed between the preliminary contact surface and the input surface of the tibia bone. The input surface model of the tibia bone in the section of interest is created by the use of the same technical feature (automatic patch) on the polygonal model of the bone, and presented in Fig. 5d. The limiting curve for the input surface section is a projected boundary curve of the preliminary surface. This means that the surface model of the proximal tibial part is divided by the limiting curve; as a result of the operation, the input contact surface of the tibia is created and presented in Fig. 5d. The deviation analysis is presented in Fig. 5e. It can be seen that maximum deviation is 1.213 mm (close to 0%, this means only one, or just few points), and minimum value is 0.286 mm (about 0.9%). The deviations for most points are around 1 mm or below (about 70%). These values are acceptable; yet the model is improved by the application of more supporting points in adequate areas as presented in Fig. 6a (points shown as squares). After the addition of the points the procedure

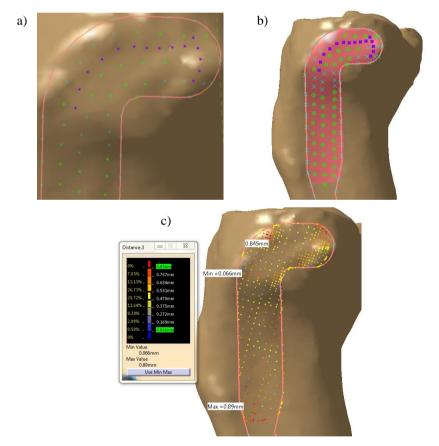


Fig. 6 Definition of MIF-LTP contact surface with additional parametric points:a) Additional points (square);b) New surface model with added points;c) Deviation analysis between input and newly created surface models

is performed again and the deviation analysis is done for the improved contact surface. The results are presented in Fig. 6c. It can be seen the maximum deviation for the improved surface is below 1 mm, precisely 0.89 mm. The deviations around 0.5 mm are about 70% of all the deviations which is more than enough as confirmed by experienced medical workers included in this research. These points are accepted as the parametric points for the definition of the parametric contact surface of the MIF-LTP. Of course, additional testing with more tibial samples will be performed in the future research in order to improve the quality of contact surface of the MIF-LTP proximal part.

The solid model of the proximal part of the MIF-LTP is created by adding thickness to the created contact surface. By applying classical technical features of trimming and merging with already created solid model of distal part of the MIF-LTP, the solid model of the whole fixator is created.

4. CONCLUSION

The methods presented in this paper enable the creation of surface, solid and parametric geometrical models of the Mitkovic type Internal Fixator for Lateral Proximal Tibia (MIF-LTP). They enable the creation of the Optimal Parametric Model (OPM) and Parametric Points Model (PPM) of the MIF-LTP. Both geometrical models can be used for Dynamic Compression Plates (DCP) and Locking Compression Plates (LCP) with adequate geometrical accuracy and anatomical correctness. OPM is good choice when there is a requirement to quickly create an implant's geometrical model because its geometry can be adjusted to the patient's bone by simply changing the values of defined radiuses. In this case, the implant inner surface will not follow the bone outer surface exactly, and the locking screws will have to be implemented in the model in order to achieve LCP fixation stability. PPM is adequate choice when there is enough time for the fine adjustment of the fixator geometry. In such cases PPM can be modified to achieve both LCP and DCP fixation by modifying the position of the anatomical and structural points.

These models can be used for the manufacturing of customized implants, for the creation of preliminary models for the FEA analysis, for the preoperative planning in orthopaedics, and for other applications in medicine and engineering.

The authors are aware that the current number of bone samples and parameters is not sufficient for the final claim about general application of the created fixator models. This would require an increasing number of input bone samples as well as to include more parameters; this would hopefully be done in the future for both OPM and PPM of the MIF-LTP.

Currently, the geometry of only one mode of the Mitkovic type internal fixator is analyzed. In the future work more fixation implants will be designed and parameterized. In that way database of geometrical models of internal fixators can be made and used when it is necessary.

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