Expert system for the production of personalized cloverleaf plate implant for human humerus

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Abstract. The Expert framework for the Development of Customized Cloverleaf Plate, model is developed and introduced in this paper for the purpose of proper plate selection, and description the geometry and morphology. The Expert System consists of a User Defined Function (UDF) for the development of a customized geometric plate model and a small-scale Expert System for the selection of the correct production method. UDF depends on the model of parametric developed, of the plate implant, which is updated in this research. Expert system is a system which is currently based on the expert knowledge, but additional improvement is scheduled for the following period, e.g. machine learning application. The Expert Framework will give great benefits for the doctors and engineers because it will enable proper pre-operative planning, production of plate implants, end education of medical practitioners and students. By the authors opinion, the most important benefit is the established modular system for the plate creation, which means that any additional knowledge for the plate creation and application can be added and used into The Expert Framework.

Keyword: plate implant, UDF. Expert Framework, CATIA.

1. Introduction
In the orthopaedic surgery, surgeons often use internal fixation for the treatment of the patient’s skeletal system. Internal fixation presumes use of osteofixation material inside the patient’s body, in order to properly stabilize bone and to enable patient’s recovery [1-3]. To properly apply procedure of internal fixation, several steps need to be performed:
Main step is selection of proper plate implant. There are two possibilities for plate selection Customized or standard plates.
If standard plates are utilized, then it is important to determine whether to apply pre-contoured or other standard plates (e.g. angular, reconstruction). In this case personalization of plate means, pre-contouring or pre-bending pre-operative or intra-operative [4-7].
If Customized plate models are required, then creation of geometrical and production plate model must be performed. These plate models are geometrically and morphologically adapted to the patient’s bone [6,7].
• Preoperative planning by using geometrical models of the plates and bones [8-11].
• The surgery, and post-operative recovery.
standard plate's Pre-bending or the use of pre-bending plates depends on the type of plate and the type and location of the fracture and is not always necessary [12-14]. If the geometry and morphology of the plate
implant is needed for personalization and customization, Then the doctors and engineers have to collaborate together to create plate implants customized to individual patients. This presumes choose the implant material, creation geometrical model, manufacturing corporal model. the production of the physical model [15]. The plate is implanted in the patient’s body and control the post-operative procedure.

2. Creation (UDF) User defined Feature to customized plate implant
As a parametric model, the geometric prototype of personalized plate for patient was built and presented in [17]. The parametric model is a geometric model that can change the geometry according to the parametric values, while the topology is the same [10]. In the following section, a brief explanation of the specified parameters will be given in order to better understand the research subject. There are two types of parameters, construction and positioning. Construction parameters define the geometry of the personalized volume model, and positioning parameters define the orientation and position of the volume model in 3D space. Parameters are defined in the AP plane of the humerus bone and presented in the Fig. 1. and Table 1.

(a) Basic parameters in AP plane  
(b) Mwidth and Lateral-Medial Angle-LMA
c) Transverse Angle – TA

Figure 1. Plate construction parameters defined on the 3D model of humerus bone.

Table 1. Parameters of the humerus bone parametric 3D model

| No | Name of the parameter | Definition |
|----|-----------------------|------------|
| 1  | Rdmax | Maximum radius defined in AP plane in the distal part of the plate |
| 2  | Rpmax | Maximum radius defined in AP plane in the proximal part of the plate |
| 3  | Mwidth | This value determines the maximum area coverage in the humerus head section for the proximal part of the plate. |
| 4  | Ri | Selected curve (circle arcs in this case) radiuses along the bone proximal part, and between Rpmax and Rdmax. |
| 5  | LMA | Lateral-Medial Angle defines rotation of the created model around axis in LM plane. |
| 6  | TA | Transversal angle defines rotation of the model around axis in transversal plane. |

Rpmmax and Rdmax describe the beginning and finishing curve radii, and Mwidth is set so the region coverage of the proximal head must be specified (it's like defining the circle tendon), i.e. how the outer surface of the proximal humerus is covered by the broad plate. All these values we utilize to establish the first surface pattern of the touch surface between both the bone and the plate. The regular thickness of 2mm was applied to the surface to create the solid model of the plate. (Fig. 1b). The overlap between the polygonal humerus model and the plate's surface prototype was present, so the required transference of the position of the plate has to be applied. The plate touch surface was typically directly rotated around a plate axis (LMA)Lateral-Medial Angle)) around 11 °, from the Lateral-Medial (Sagital) plane for 1 mm. The plate axis is defined as the line between the middle point of the broadest part of the proximal part of the plate (Mwidth) and the middle point at the RDM5X location (distal end of the plate) and is located in the humerus bone plane LM (Lateral-Medial) (Fig.1b). Another rotation around the axis located in the humerus transverse (axial) plane, placed just below the metaphysics. The point on the anatomical axis passes through this axis and the AP plane is regular. The angle of rotation is the transverse angle and it's0.5o(Fig.1c). As a
result of the application of the parameters, a solid model of the personalized plate was designed and correctly placed to match the outer surface of the humerus bone.

3. **User Defined Feature created for the parametric plate model**

The User Defined Function (UDF) in CATIA was built based on the parametric model generated. The User Defined Function is a form function that operates at the component level. You can create and add a set of features (formulas, geometry, constraints, literals, etc.) like any other CATIA function. You can save the created function in a catalogue (database) and reuse it later. In order to construct UDF, parametric model geometry is extracted for the purpose of creating UDF, and generated in a particular geometric set under the body entity, Fig 2. For creating suitable UDF feature, just three components were necessity as Components inputs are: the first origin is an Axis system and a second origin for an Axis System, Anterior Posterior (AP) plane and Transversal Plane. First and Second origins were chosen as input elements to exactly position the plate model. The first origin represents to the centre of gravity of the bone and the second origin represents to the distance i.e. a distance vector of model from its centre. AP planes and Transverse are utilized for correctly orient the plate model in space to improve the orient of the plate sample in space.

![UDF for the modified plate implant](image)

**Figure 2.** UDF for the modified plate implant
When constructing a particular bone model, all input components are generated, so it is important to have a convenient customized 3D bone model together with specified Referential Geometric Entities (RGEs)\cite{17} in order to apply UDF. Using any known method, and MAF \cite{10}, you can build that kind of model.

It is not only sufficient to set the input components to properly construct UDF. At the time of model creation, it is important to decide which parameters of model modification are accessible to the user. If we do not define these parameters, the 3D model of the plate cannot be modified by the UDF user, and there would be a loss of UDF application advantage. These parameters were radius and \textit{Mwidth} for the first UDF provided in Fig 2. This description of UDF is normally very right, but some problems occurred during the testing process. Proper alignment of the individual arcs was the most significant issue—it was not feasible, just radius values can be changed. If the user wishes to alter the geometry and shape of the plate model by shifting arcs through space, it is not feasible and should be made available to the expert (surgeon) opinion. The updated parametric model with few geometry description changes was developed to resolve this issue. It is still possible to use the original model with specified radii (Fig. 1) and \textit{Mwidth} as a separate UDF, of course. Some changes to the basic building geometry of the plate implant were made in order to gain more control over the shape of the model. Contrary to the primary design geometry of the plate implant was made in order that get extra control in a shape of the model. Contrary to the primary model, the key difference being that individual circle arcs were described as two points with arcs and an arc angle. Initially, points still lie down in the Anterior Posterior plane and they describe radii, the original model, the main difference being that singular circle arcs were described as arcs with two points and an arc angle. Initially, points still lie in the AP plane and they describe radii, but if there is a necessity, they can be converted to another location. The arc angle added is a parameter that determines the width of the plate at any arc circle, as shown in Fig 3. So, four parameters are more accuracy than one parameter. Therefore, the circle arc position in 3D space is better mark. The support plane (fourth parameter) is a plane generate using the transverse plane and the AP plane, as shown in Fig 3. Then, the all geometry of the plate is described and intend for use.

![Figure 3. Description of the circle arc, start, end points, and angle of the arc. +7](image)

For each given radius parameter, this procedure was performed and the UDF user be free using these parameters (start point, end point and arc angle) for future use. By modifying the values of the parameters,
both UDFs (original and improved) were tested and various shapes were obtained without topology defects, thus UDF definitions can be classified as valid for the present study stage.

4. Techno economic analysis to cloverleaf implant and Manufacturing processes
A good choice for patient care is a customized geometric 3D plate model, but surgeons would not have anything to inject into the patient’s body without a physical model. As is already established, there are several possibilities for the development of plates, and with the suggested suggestions, an expert framework was developed to be able to select adequate technology. Depending on the individual medical case and specifications, what equipment can be used. It is important to note that significant processes affect the collection, modification (through UDF) and development of implants. In Fig 4. these processes are presented. and they're self-explaining.

![Figure 4. Scheme of the method of treatment](image)

Three production processes are specified for the purpose of producing a customized plate (implant) and they are:
- Traditional production: shaping and machining of metals
- Additive Technologies: Targeted Sintering of Lasers
Technological processes are specified in Table 2 and relevant technology operations are listed.
Table 2. Personalized plate manufacturing process (Ti6Al4V)

| Metal forming                          | Machining                                    | Selective laser sintering (SLS) |
|----------------------------------------|----------------------------------------------|----------------------------------|
| 1. Definition of the stock (panel sheet) | 1. Definition of the stock (panel sheet)    | 1. Preparing the model geometry in CAM software |
| 2. Stock cutting to adequate size       | 2. Surface Milling of the defined geometry (from both sides) | 2. Creation of the fixator model at the SLS printer. |
| 3. Bending in the adequate tool         | 3. Hole drilling                              |                                  |
| 4. Making adequate holes in the same tool | 4. Grinding of the external and internal edges |                                  |
| 5. Grinding of the external and internal edges |                                  |                                  |

5. Analysis of Multi Criteria
For the multi-criteria analysis of a manufacturing processes, the Fuller Triangle for all stated criteria is identified and is shown in Fig.5. In order to explain the standards, two experts will be consulted. 10 pair triangles are described with the value within each criterion defined for the five criteria as 10 percent. For proposed technologies, all the values of the requirements are specified and shown in Table 3. The last criterion values are determined on the basis of the value of the criteria and the particular value of the criterion for each production technology proposed. The arithmetical average of individual grades for both experts was determined.

![Figure 5](image)

Figure 5. Define the importance of each criterion, the Fuller triangle method

Expert ratings, calculations and mean values are presented in the following tables (Table 3 -5). They describe the basis of the recommendations for technology. The actual manufacturing technology that will be selected in the specific medical case often depends on other factors, such as technology availability, technology access, manufacturer power, etc.
Table 3. Expert grades

| Technology | First Expert | Second Expert |
|------------|--------------|---------------|
| **Metal Forming** | Specific Values |                |
| TIME       | 4            | 3             |
| QUALITY    | 3            | 3             |
| FLEXIBILITY| 3            | 3             |
| MATERIAL   | 4            | 4             |
| EXPENSES   | 1            | 2             |
| **Machining** | Specific Value |           |
| TIME       | 3            | 4             |
| QUALITY    | 4            | 4             |
| FLEXIBILITY| 3            | 3             |
| MATERIAL   | 3            | 2             |
| EXPENSES   | 3            | 4             |
| **SLS**    | Specific Value |            |
| TIME       | 4            | 5             |
| QUALITY    | 5            | 4             |
| FLEXIBILITY| 4            | 5             |
| MATERIAL   | 4            | 4             |
| EXPENSES   | 3            | 3             |
**Table 4.** Calculated values for given parameters and production technology (values of significance * particular values)

| Manufacturing technology | TIME | QUALITY | FLEXIBILITY | MATERIAL | EXPENSES |
|--------------------------|------|---------|-------------|----------|----------|
| First Expert             |      |         |             |          |          |
| Metal forming            | 1.2  | 1.05    | 0.15        | 0.8      | 0.1      |
| Machining                | 0.9  | 1.4     | 0.15        | 0.6      | 0.3      |
| SLS                      | 1.2  | 1.75    | 0.2         | 0.8      | 0.3      |
| Second Expert            |      |         |             |          |          |
| Metal forming            | 0.9  | 1.05    | 0.15        | 0.8      | 0.2      |
| Machining                | 1.2  | 1.4     | 0.15        | 0.4      | 0.4      |
| SLS                      | 1.5  | 1.4     | 0.25        | 0.8      | 0.3      |

**Table 5.** Mean values for defined criterions and manufacturing technology (importance value * specific values) for both experts.

| Manufacturing technology | TIME | QUALITY | FLEXIBILITY | MATERIAL | EXPENSES |
|--------------------------|------|---------|-------------|----------|----------|
| Metal forming            | 1.05 | 1.05    | 0.15        | 0.8      | 0.15     |
| Machining                | 1.05 | 1.4     | 0.15        | 0.5      | 0.35     |
| SLS                      | 1.35 | 1.575   | 0.225       | 0.8      | 0.3      |

6. **Discussion of findings**

Estimated values are provided in Table 5 for all listed production technologies and established parameters. The values are descriptive, but it is important to note some remarks:

- Time for SLS applications, time is minimal. This is popular since components can be easily generated if all is scheduled correctly.
- Quality Machining is very close to that except for SLS technology, the best. This is affected by certain factors, so much further research in some subsequent studies should be carried out.
Flexibility For SLS, the better, but for personalized plates, this is not so significant.

Material: (production waste) for machining is high, while there will be less waste in SLS and metal forming. But since there are several variables influencing this criterion, this is questionable (type of stock, design intent, etc.).

Expenses for metal forming are large because the tools for shaping operation are very expensive when manufacturing only one implant. This is the reason it makes it cheaper for machining and SLS.

7. Applying the parametric model to the sample utilization case.

The case of sample usage representing proximal decrease and fixing of humerus was acquired from [18] and shown in Fig 5. This example simulates a medical case and illustrates the applicability of the expert system proposed to describe and create the customized plate model.

![X-ray image of humerus fracture and plate fixation](image)

Figure 6. Proximal humerus fracture X-ray images of plate fixation.

The use case was chosen because the whole procedure, from diagnostics to aftercare, was undertaken for the treatment of the fracture. Four processes were conducted in order to perform plate personalization. These procedures are shown in Fig. 6.

![Diagram of plate personalization process](image)

Figure 7. Process of Create a custom plate model for humerus.
Process P1 was carried out, in order to rightly get parameters from the X-ray image. Appropriate bone reduction was important. To simulate bone reduction, transformation of 2D image parts in GIMP software was performed and presented in Fig 7a. The correctness (procedure) of the image transformation was checked against the image of the bone already fixed and shown in Fig 7b.

![Figure 8](image)

**Figure 8.** The definition of the X-ray scan geometry of a plate and the parametric model of the generated plate.

Utilizing humerus and plate 3D models already established, processes P2 and P3 were carried. To obtain the required parametric worth for both the parametric model customization, the plate and bone assembly are combined with the transformed image. All measurements have been performed on the AP plane, i.e. the X-ray image plane, in the P3 process. This plane corresponds to the AP plane developed on the 3D humerus model by CATIA software. In the X-ray image, calculated values were scaled according to the set etalon. The calculated values and location of the corresponding points were passed to the CATIA and also the parametric model was translated and adapted to the specific bone process using the already produced UDF (process P4). The user form was developed in order to implement UDF, and presented in Fig. 8a, which requires the use of UDF in the CATIA component or assembly module. The UDF form allows:

- Immediate UDF element insertion into the model of the component or assembly - "Insert UDF plate" button
- Adjust the UDF position in the component space with the "Define UDF position" button
- Acquisition parameter values from the Excel Template Table - Get Data from Database button

UDF was implemented using this form and a 3D model of the customized plate was developed. We simulated SLS using FFF (FDM) 3D printers to build physical models, just to check if everything was in order. The written model in Fig. 8b.
8. **Conclusions**

For orthopaedic equipment, plate implants are required and their development and manufacturing processes should be significantly improved. In this manuscript we presented the techniques that make it possible to create and produce a customized cloverleaf fixation plate. The main benefit of this method implementation is the ability to individually generate implant models modified (personalized) for each patient, using expert expertise and user specified features. This path is based using the MAF procedure and more specifically, in order to create a parametric plate model, the method extensions are defined by adding and defining the corresponding parameters. By adding and adjusting the value of the current parameters according to the dimensional values obtained from the 2D or 3D humerus bone model, pre-contouring, i.e. plate adaptation, is achieved whereas the topology is same. It is possible to adapt the plate model via the UDF framework generated by CATIA. UDF allows the values of the parameters to be inserted, the shape and geometry of the plate models are also personalized for the specific customer. The UDF application is provided with an example identified by the clinical status, which is freely available online and with two additional test examples obtained separately. The results show that the criteria raised can be met very satisfactorily.

The probability of plate adaptation enhances preoperative procedures, shortens the time of intervention, makes fracture firmness and protects the physical characteristics of the bone and joints. It should be noted that having a geometrically accurate plate model is not always necessary, but the development of a versatile model is important. If the parametric model can indeed be flexible enough even to adapt to the particular situation, bending must not be used by the surgeon during the operation.

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