The introduction of customization at the CAD project stage. The assembly counted 10 different input parameters. Three different types of medical screws have been developed in the application:

- The Herbert Screw
- Cancellous Screw
- Malleolar Screw

With the SolidEdge system using an API, taking into account 10 different input parameters. Three different types of medical screws have been developed in the application: the Herbert Screw, Cancellous Screw, and Malleolar Screw with three different thread types: rectangular, isosceles, and trapezoidal. The screws designed in this way can be manufactured using 3D printing techniques or CNC machining, and can be used for both humans and animals.

Keywords: CAD automation, customization, medical screw, 3D printing

Customization is the adaptation of a product to the individual needs of a client, in this specific case a patient. Currently, standardized surgical screws with specific lengths, diameters, and thread pitches are available on the market. Until now, a partial solution to this problem has been the release of several series of medical screws embedded: on the left – in a ankle; on the right – in a finger.

When it comes to the length of medical screws, there is a wide variety on the market, while other parameters such as the shape of the thread and the thread pitch are not.

The presented solution may also be useful in conducting research consisting in selection of the parameters and shape of a medical screw based on the individual bone’s properties. One can imagine research in which different screws are selected. When it comes to the length of medical screws, there is a wide variety on the market, while other parameters such as the shape of the thread and the thread pitch are not.

The process of customization itself is characteristic of handmade products, not automatic, e.g. furniture made to individual customer orders. In mass production, the scope of customization is very limited and comes down to the configuration of the equipment of the same product, e.g. the selection of different equipment options of the car. Thus understood, customization takes place at the very end of the whole process, after the production stage.

What if we reverse the order and introduce customization at the very beginning of the production cycle, i.e. in the project stage? It is then possible to influence the parameters of the final product. Designing can also be very laborious with each individual customer order. The whole idea of this approach, however, lies in automating the customization process, means automating of creation the CAD project.
The presented solution focuses on surgical screws, of which 3 types have been selected: the Cancellous Screw, Herbert Screw, and Malleolar Screw (see figure 3). However, nothing prevents other types of screws from being implemented in the program generating the CAD projects, e.g. the Cortical Screw, the more complex Mono Axial Screw, or even the Poly Axial Screw.

![Medical Screws](image)

Fig. 3. Medical screw types: Cancellous Screw, Herbert Screw, Malleolar Screw

The presented customization of medical screws concerns 10 parameters, which are:
1. Bone Screw Type:
   - Cancellous Screw, Herbert Screw, Malleolar Screw.
2. Screw Length,
3. Screw Diameter,
4. Pin Radius,
5. Thread Pattern: rectangular, isosceles, trapezoidal (see Fig. 4),
6. Thread Thickness and Head Thread Thickness for Herbert Screw,
7. Thread Pitch and Head Thread Pitch for Herbert Screw,
8. Head Radius,
9. Head Length.

![Thread Pattern](image)

Fig. 4. Customization of the thread type: a – rectangular, b – isosceles and c – trapezoidal

It should be noted right away that it will not be profitable to do this for every type of product, and in some cases, it may not be possible at all. In this case – the production of medical screws – however, customization seems to be an ideal solution. The production costs of a product designed in such a way are not without significance. When using resin or metal 3D printers, however, they do not seem to be overly high [6, 8].

2. Development

In order to implement customization at the project stage, you can use CAD (Computer Aided Design) software. For this, you will need an application that controls the CAD system and generates projects in it automatically, based on the input parameters set. Such a control application should be custom-written [1].

The application would use OLE (Object Linking and Embedding) technology to communicate with the SolidEdge CAD system. Simply put, OLE is a mechanism for embedding objects in applications that allows you to control these objects using an API (Application Programming Interface). Using this technology, it is possible to create an application that controls a design support system, such as SolidEdge or another system from the PLM (Product Lifecycle Management) family, e.g. AutoCad [5, 12]. The control application for generating CAD projects in the SolidEdge system is presented in figure 5.

![Control Application](image)

Fig. 5. Control application for generating CAD projects with a list of input parameters

The control application that we use to embed the OLE object in the CAD program can be written in any object-oriented language, such as C#, C++, Visual Basic.NET or Java [4, 5]. These objects are made available in the form of a DLL (Dynamic Link Library). Most of the producers of CAD or PLM software provide such libraries. In order to generate custom CAD projects, the following is required in the control application:
- adding a DLL library to the project
- DLL library support
- creating an object that will be linked to the CAD system
- calling methods of a CAD object: eg.: creating a project, drawing parts of an assembly
- converting and saving the project to a file format for 3D printing.

Listing 1 shows how to use the AutoCad OLE object in the C# programming language.

Listing 1. An example of using the AutoCad OLE object in the C# programming language

```csharp
try {
    Object acadApp=Marshal.GetActiveObject("AutoCAD.Application");
    if (acadApp == null) return null;
} catch (System.Exception ex) {
    result = null;
}
```

We can use the OLE object of SolidEdge in a very similar way (see listing 2). We purposely included two examples for different PLM systems, and in different programming languages, to show that the desired result can be achieved in many ways. In the following part, for better readability and understanding, the focus is on presenting listings only in one programming language – Visual Basic.NET [5].

Listing 2. Example of using a SolidEdge object in the Visual Basic.NET programming language

```vbnet
On Error Resume Next
objApp = CreateObject("SolidEdge.Application")
If Err.Number > 0 Then
    Err.Clear()
objApp.Visible = True
End If
```

After accessing the CAD program object, the only thing left to do is to use the methods provided by this object. First, you need
to create a project object – SolidEdge.Application – and then an assembly object – SolidEdge.AssemblyDocument – in which the assembly will be added – SolidEdge.PartDocument. This section of the program is covered in listing 3.

Listing 3. Creating assembly and part objects for SolidEdge in Visual Basic.NET

```
objDoc = CType(objApp.Documents.Add("SolidEdge.PartDocument"), SolidEdgePart.PartDocument)
objAssembly = CType(objApp.Documents.Add("SolidEdge.AssemblyDocument"), SolidEdgeAssembly.AssemblyDocument);
```

The complete assembly may consist of several, or several dozen elements – parts that are created by extending, rotating or cutting basic figures, i.e. a circle, a rectangle, a triangle. An example of creating such an element by extruding is the AddFiniteExtrudedProtrusion method presented in listing 4.

Listing 4. Creating an assembly element by extruding in Visual Basic.NET using the AddFiniteExtrudedProtrusion method

```
objModel = objDoc.Models.AddFiniteExtrudedProtrusion(
    NumberOfProfiles:=1, 
    ProfileArray:=objEPProfArray, 
    ProfilePlaneSide:=t, 
    ExtrusionDistance:=d
)
```

To create parts by rotating, you can use the AddFiniteRevolvedProtrusion method. However, the most difficult part to develop is the screw thread. This is done with the AddFiniteBaseHelix method, as shown in listing 5.

Listing 5. Creating a screw thread in Visual Basic.NET using the AddFiniteBaseHelix method with example calling parameters

```
objModel = objDoc.Models.AddFiniteBaseHelix(
    HelixAxis:=objBRAxis, 
    AxisStart:=igStart, 
    NumCrossSections:=1, 
    CrossSectionArray:=objBHCSArray, 
    ProfileSide:=igRight, 
    Height:=0.0, 
    Pitch:=x, 
    NumberOfTurns:=pr * 2 * Math.Sqrt(3) / 2 / s, 
    HelixDir:=igRight, 
    TaperAngle:=k
)
```

A project created in this way can be programmatically saved to a file in the STL (Stereolithograph) format, i.e. in the form of a triangle mesh.

3. Use cases and results

The complete custom manufacturing process for 12 different medical screws is shown as an example of use. The complete production cycle consists of 3 steps:

- customization – entering the parameters into the program,
- generating a CAD project – creating a project in the SolidEdge program,
- 3D printing – printing elements in a 3D printer, e.g. LCD-based SLA type.

In the first step, 4 different configurations were introduced for each of the 3 types of screws, and which gives us 12 different CAD projects as well as 12 completely different 3D prints. The possible combinations of these 10 customization parameters are of course endless, so the focus was on those that show the possibilities of the proposed solution and the diversity of the final product.

A Cancellous screw CAD project was generated first. The screw parameters enter figure 6.

Fig. 6. Generated CAD projects of Cancellous Screw

These screws were then printed on an LCD-based SLA 3D printer. It should be noted that this printout is intended to show the final effect of the complete process, but it is not made of a material used in medicine (see figure 7).

Fig. 7. 3D print of Cancellous Screws on an SLA printer

A CAD project was then generated for Herbert screws. The screw parameters entered into the program are visible directly under the drawings (see figure 8).

Fig. 8. Generated CAD projects of Herbert Screw

Finally, a CAD project was generated for Malleolar screws. The screw parameters entered into the program are visible directly under the drawings (see figure 10).

The 3D prints will look as are shown figure 11.
The time to generate a CAD project from entering the customization parameters is a few minutes. The screws were printed in 3 rounds, the shorter screws were printed vertically and the printing time was no more than 3 hours. The long screws were printed horizontally or at an angle with a support and then the printing time was about 4 hours. 3D printer tables with various of print layouts are presented in figure 12.

4. Conclusions

The presented process of customization of the production of medical screws – from parameterization, through project generation, to 3D printing – has been successfully completed. The generation of the CAD projects, including entering the input parameters, only took a few minutes. Printing with a 3D printer takes a few hours, of course, and this depends on the type of printer and material used. In this specific case, printing of all screws took no more than 4 hours. It is enough to use only the appropriate materials, e.g. titanium, so that they can be used in specific medical cases. More advanced CNC machines would also be able to manufacture such screws by machining. However, this is not the essence of this idea. The conducted research shows that customization can be quite easily transferred from the post-production stage to the CAD project stage. If we use appropriate methods of manufacturing these products directly from the CAD project, we produce almost unlimited customization possibilities. Most cases can be carried out with a standard product that is generally available on the market, but there are also medical cases for which such a method may be the only way to obtain screws with the expected parameters [3].

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