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Two different techniques of manufacturing TMJ replacements – a technical report

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Introduction

At present, various medical implants in maxillofacial surgery, from stock-type implants to custom-made ones, can be used in the surgical treatment of patients. Since the 1960s, total temporomandibular joint (TMJ) replacements have consisted of highly biocompatible materials such as Cr-Co-Mo alloy, titanium and ultra-high-molecular-weight polyethylene (Mercuri, 1998; Driemel et al., 2009; Westermark et al., 2011).

Contrary to stock-type prostheses, which are provided in various sizes and shapes (Lee et al., 2013), patients can obtain specifically customized implants via computer-aided design/computer-aided manufacturing (CAD/CAM). With so many differences in the structure and shape of the human skull, it is difficult to replace the joint successfully without a highly customized replacement (Chaware et al., 2009).

The aim of this study was to present, for the first time, clinical and technical information on temporomandibular joint replacements where custom-made implants were manufactured using two different techniques.

Materials and methods

The study was approved by the Human Investigation Bioethical Committee of the Medical University of Lodz (RNN/266/11/KB, RNN/312/12/KB, RNN/739/12/KB). The consecutive series consisted of seven men and four women, with an average age of 54.0 ± 15.5 years. All of the patients underwent TMJ reconstruction with custom-made implants, using the copyrighted direct metal laser sintering (DMLS) or the computer numerical control (CNC) milling technique. Four of the 11 patients (two males and two females) had neoplastic lesions in the mandible or directly in the TMJ; one (male) had an advanced degenerative-inflammatory lesion of the TMJ; two (male) had fibrous dysplasia; one (female) had an injury after a car accident 4 years earlier; and one patient had ankylosis. The patients complained of hypomobility of the TMJ (decrease in the maximal interincisal opening (MIO) – Table 1), facial asymmetry, and swelling of the TMJ area. Under physical examination, three patients (two affected by tumours and one after the car accident) reported pain and facial asymmetry through augmentation of the preauricular area. In one patient, facial palsy was noted pre-operationally. The degenerative-inflammatory lesion did not induce facial asymmetry due to the disease developing in adulthood.

The first stage was to create a 3D image of hard tissue using computer tomography (CT) scans. The scan thickness varied from 0.6 mm to 1.0 mm. The volume of interest included the whole mandible up to the temporal bone in the lateral aspect and midface in the central aspect. CAD work was performed using MIMICS (Materialise, Leuven, Belgium) to perform segmentation, and GeoMagic (Geomagic Corp., USA) to verify the quality of the implant surface. Any defects/pseudoforamina were repaired using the specialized tool Geomagic Studio 14 and SolidWorks (Dassault Systèmes SolidWorks Corp., USA) in the design of the acetabulum and condylar implant, using the mirror technique, once the positions for implant fixation were designed (only unilateral cases were included in that project). The supporting structure of the implants had to be designed based on the virtual model (3D-CAD) and using appropriate software. This secures the constructed elements and allows for the precise removal of implants from the platform without any surface damage.

3D surface bone data were obtained and exported as a *.3ds file. Next, the prosthesis was performed using the DMLS or CNC technique (Figure 1 and Figure 2). Both techniques are different; the manufacture stages are presented in Figure 3.

Materials used for TMJ replacement production were medically certified for human implantation:

1. Acetabulum part: ultra-high-molecular-weight polyethylene (UHMW-PE), according to ISO 5834-1 2007 type 1, ISO 5834-2 2006 type 1, and ASTM F 648-07 type 1.
2. Condylar part:
   a. Block of titanium alloy Ti6Al4V – extra-low interstitial, according to ASTM F136, ISO 5832-3, and BS 7252-3 for milling.
   b. Powder of titanium alloy Ti6Al4V for direct metal laser sintering, according to ISO 5832-3:1996.

For the CNC technique, the milling strategy and types of tool were carefully selected to achieve maximum accuracy in the resulting physical implant. Burs of diameter 4 mm, 2 mm, 1 mm, and 0.5 mm were applied one after the other in the three-axis milling device (KIMLA BFN-40, Poland). The cutter movement was from the centre to the periphery of the implant surface. Rotations were selected for each material (16,000 rpm for the titanium alloy, and 4,000 rpm for polyethylene). Later, the milled polyethylene parts were cleaned, and their borders were thermally rounded for the polymer acetabular part. The titanium parts were polished in the condylar head region and sandblasted in the last part of implant (glass spheres with a 100-μm diameter). An ultrasonic cleanser was used before sterilization. The metallic parts were marked by a laser (patient name, date, department name, and university logo).

DMLS production was based on 3D-CAD data in the form of .stl files, which are necessary for the printer software designed to prepare the data for production. Using AutoFab, a division into layers could be performed. The sintering process was carried out on the steel platform. A dosing device set the quantity of powder (a wide range of powders – from light alloys to super alloys – and composites are available in the DMLS system), and a ceramic blade spread it layer by layer.

Thereafter, metal powder was melted locally, following the contours of each layer using a focused laser beam (the fibre optic laser power was 200 W, and the beam focus point was variable from 60 μm to 300 μm). The thickness of the sintered layers in the implant was 30 μm, and the construction speed was 25 cm^3/h.. The laser beam was controlled using the *x* and *y* coordinates. Moving the steel platform gave the opportunity to adjust the *z*-axis. Next, the sintering element and platform were subjected to thermal processing to decrease the internal stresses. The process (annealing) occured at 700°C for 1 hour in a protective argon atmosphere. The element was then slowly cooled down in the furnace and subjected to the tempering process. Tempering reduces stresses, and decreases the brittleness and hardness of the annealed element. Later, the condylar part was subjected to automatic and manual polishing. (Automatic polishing has abrasive properties, while manual polishing allows proper surface roughness.) The catalogue number and size were marked on its surface (Figure 1).

Patients (Table 1) were treated by surgical procedures performed under general anaesthesia, with oral or nose intubation. Exposure of the TMJ area was made via the preauricular region and of the ramus using a submandibular or circumflexed mandibular approach. Next, parts of the mandible with pathological lesions were resected along the individual CAD/CAM cutting templates. Treatment included four total joint replacements using customized implants (mandibular implant made of titanium, using DMLS or CNC milling, with reconstruction of the acetabulum using UHMW-PE) and seven customized titanium implants of the lower part of the joint. All of the parts were fixed and stabilized using titanium screws. An artificial glenoid fossa implant was fixed with four to five 6-mm-long screws of 2.0 mm in diameter, and the condylar part was fixed with five to eight 10-mm-long screws of 2.7 mm in diameter. The wounds were fitted layer by layer.

The functional results — i.e. MIO — were statistically evaluated with Statgraphics Centurion XVI, using distribution analysis to detect normality, and a paired-samples *t*-test for pre- vs. post-treatment mouth opening and analysis of linear regression. Comparison of both techniques of implant manufacturing was performed using analysis of variance (ANOVA).

In this study, statistics consisted of MIO_pre (maximal incisal opening before treatment), MIO_post (maximal incisal opening after treatment), and MIO_improvement. MIO was checked between the upper and lower central incisor edge. The authors checked MIO_improvement dependent on age, sex, diagnosis, adjuvant radiotherapy, MIO_pre, MIO_post, follow up, and manufacturing technique (DMLS or CNC milling).

Results

The surfaces of manufactured metallic parts of implants appeared more raw in DMLS cases than in CNC milling ones. DMLS implants needed more abrasive surface conditioning before medical application, possibly influencing implant dimension stability, or requiring shape alteration during abrasive post-processing to control the implant size and surface shape. Furthermore, after DMLS manufacturing, the implants may be more vulnerable to fracture after implantation. The cause may be that titanium grains are not of equal size and structure before sinterization.

Post-operational healing was standard in all of the cases. After the operation, all 11 patients were affected by minor facial nerve palsy, which disappeared after 3 months of physiotherapy. No patients in our study experienced swallowing disorders or persistent pain. No re-ankylosis or infection of the operated site was observed. The materials that were used to produce the implants in both techniques did not cause allergic reactions. Due to the applied CAM techniques to create the implants, TMJ replacements were of the correct form, and the functions of the joint were restored. Patient age did not influence the final MIO value ($p = 0.19$). ANOVA statistics also showed that MIO_improvement was not correlated with sex and diagnosis ($p > 0.005$). However, it should be noted that patients with a malignancy diagnosis had a worse MIO_post than patients with a benign diagnosis.

Due to adjuvant treatment and rehabilitation, MIO improved from 18.0 ± 13.2 mm to 36.7 ± 7.4 mm (Table 1), a difference that was statistically significant (paired samples *t*-test: $t = -4, 16847$, $p < 0.005$). Pre-operational MIO was not related to the outcome value in (R^2 = 70, 60%, $p = 0.0329$). The correlation coefficient was −0.51, indicating a relationship (but relatively weak) between pre- and post-operational MIO. The worse the pre-operational MIO was, the better the mouth opening improvement (Figure 4). This relationship could be shown by the following equation:

$$\text{MIO\_improvement} = 66.3 - 18*\ln(\text{MIO\_pre})$$

The influence of follow-up on MIO_improvement was not statistically significant (p = 0.38; p > 0,005), and there was no correlation between the follow-up and MIO improvement.

Worse results were noted in adjuvant radiotherapy cases. ANOVA revealed no statistically significant difference ($F = 0.16$, $p = 0.69$) between maximal post-operational mouth opening and the implant manufacture technique (Figure 5).

Discussion

It is commonly known that each surgical treatment carries the possibility of short-term and long-term complications. Infection, loosening of screws or implant, implant fracture, allergy to metal, or re-ankylosis of surrounding hard tissue can be related to post-operational complications of alloplastic TMJ replacement (Sinno et al., 2010) and, in the long-term, to foreign bony response to metal TMJ replacement (Sidebottom et al., 2008). Regarding side effects, the use of customized implants, manufactured using rapid TMJ prototyping techniques, makes it possible to avoid some complications.

CT has not only revolutionized diagnosis; it also allows the accurate manufacture of TMJ implants. CT is used in CAD/CAM, which is required for both CNC and DMLS in fabricating the TMJ implants and separating material in the total replacements. CAD/CAM systems allow customized mandibular condylar implants to be designed and fabricated with the highest degree of fit and then to be perfectly fixed to the surrounding bones (Li et al., 2011). Moreover, surgeons can design the implants themselves if they want to, creating the perfect implant to meet the surgeon’s requirements and a reduction in the number of complications.

CAD/CAM systems offer a cost-effective and efficient means for surgeons to design and manufacture perfect-fit, custom-made TMJ implants (Parthasarathy, 2014), as shown in the examples presented here. In addition, they reduce surgery time and morbidity, allow better training of future doctors, and make it easier to explain the treatment aims to the patients. The main disadvantages are the high cost and availability of software tools (Da Rosa et al., 2004).

The most accurate and predictable technique is CNC milling, followed by DMLS, and then metal casting, due to the difficulty in obtaining a precise silicone impression of the operating field (Park et al., 2015). The least accurate technique is manual fitting of a stock TMJ replacement, which normally requires patient bone modification to fit to the implant, in contrast to a patient-specific, customized implant.

With the developing technology, custom-designed implants provide better outcomes and fewer side-effects in adults; however, until now, there has been no gold standard for TMJ replacements (Chaware et al., 2009; Sinno et al., 2010; Westermark et al., 2011).

Based on the available scientific background sources (Mercuri, 1998; Da Rosa et al., 2004; Sidebottom et al., 2008; Driemel et al., 2009; Chaware et al., 2009; Sinno et al., 2010; Westermark et al., 2011; Li et al., 2011; Lee et al., 2013; Parthasarath, 2014; Gonzalez et al., 2016), follow-up treatment, and a limited number of patients, custom-made implants made using DMLS or CNC are the best option in reconstruction of the TMJ. Patients have limited post-operational, permanent side-effects. The presented reconstruction possibilities can be used for any TMJ defects, and where systemic disorders affect the functions of the TMJ. The surgeon's choice of manufacturing technique depends on the specific operative procedure, the available fabrication facilities, and the likely benefits for patients.

Conclusion

When considering both CAD/CAM methods from the perspective of the surgeon, the feature that differentiates the manufacturing techniques required is the more subtractive surface finishing required for DMLS implants compared with CNC milling, leading to a rougher surface of the condylar implant in DMLS. With its greater precision and lower costs, DMLS could be the system of choice for future implant manufacturing; however, this technique brings a greater chance of implant failure. The treatment results in this study suggest that both techniques (DMLS and CNC milling) result in the same clinical outcomes. Both manufacturing techniques can be used successfully in patients affected by neoplastic lesion and other TMJ disorders that require alloplastic reconstruction.

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Legends to the figures and table

Table:

Table 1. Clinical summary of 11 patients who underwent surgical treatment and customized alloplastic TMJ reconstructions.

Figures

Figure 1. (Top) Virtual model of a customized implant made using a CAD system (grey areas – supporting regions, i.e. glenoid fossae and occlusal dentition; red area – affected hemi-mandible; green area – intact hemi mandible; brown – computer-designed implant]. (Middle) An implant milled with titanium alloy using a computer numerical control device, showing holes for fixing screws and for muscle attachments. (Bottom left) Temporal ultra-high-molecular-weight polyethylene part of an implant fixed by four screws to the cranial base. (Bottom right) Titanium alloy (grade 23 ELI) implant (ascending ramus and angle, with condylar head fitted to the socket). Note the stitches fixing the temporalis muscle insertion and lateral pterygoid muscle.

Figure 2. (Top) CAD implant model of the ramus and condyle process (green area – lower mandibular; blue area – acetabular implant, i.e. the cranial part of the implant). (Middle) Titanium alloy (grade 23 ELI) implant, made using a DMLS system. The inner surface of the implant is rough as a result of sinterization. (Bottom left) UHMW-PE acetabulum fixed using 2.0 mm screws, with a fitted condyle process. (Right) The condyle process, fixed using five 2.7 mm screws.

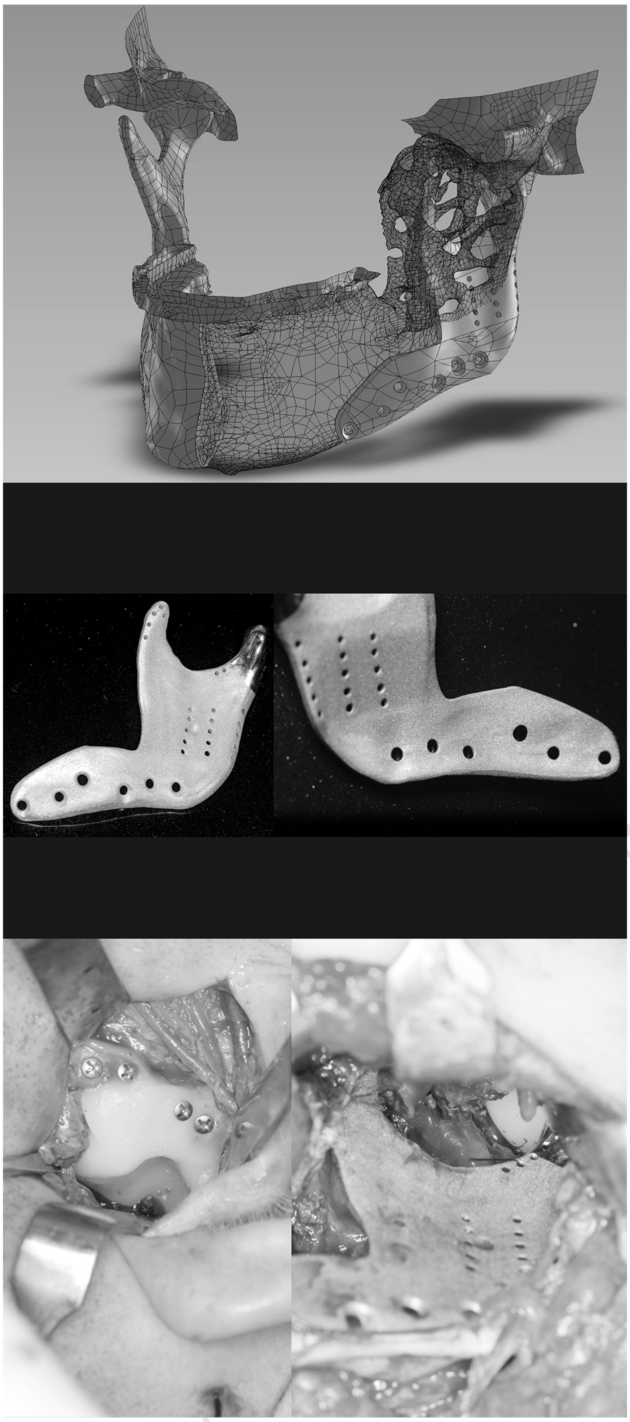
Figure 3.Stages of, and differences between, CNC and DMLS.

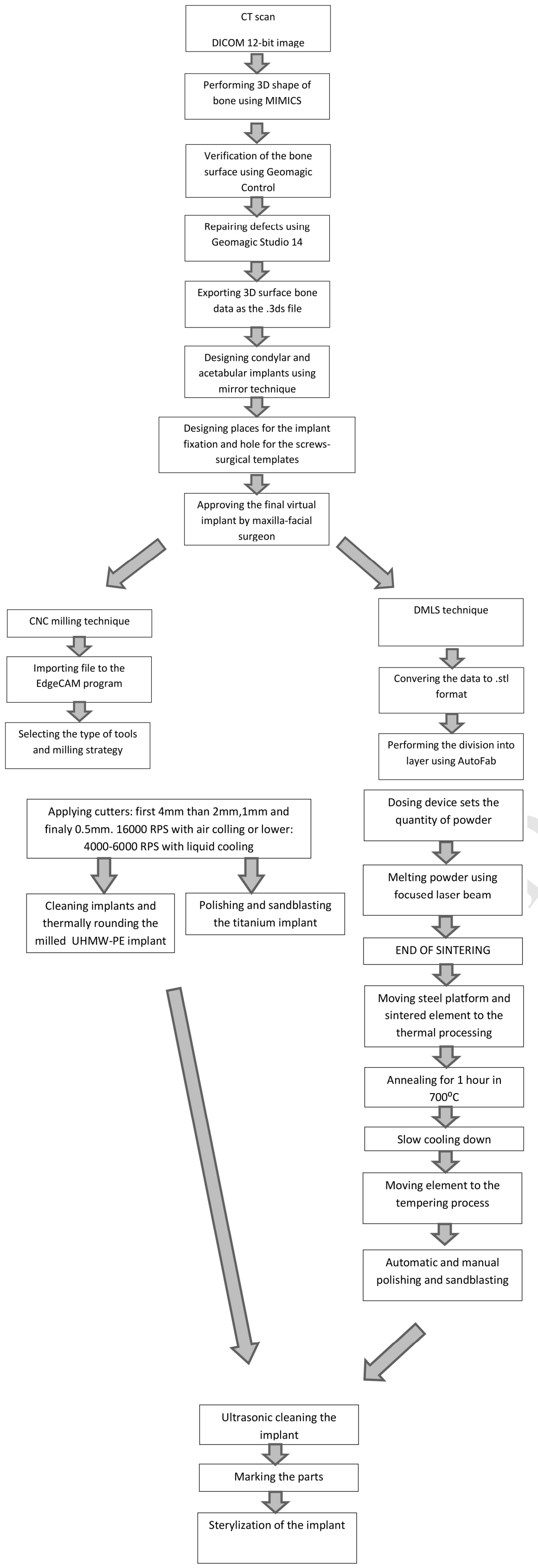
Figure 4. A comparison of functional results according to method (CNC or DMLS) of TMJ implant manufacture. Statistically speaking, both techniques led to the same results.

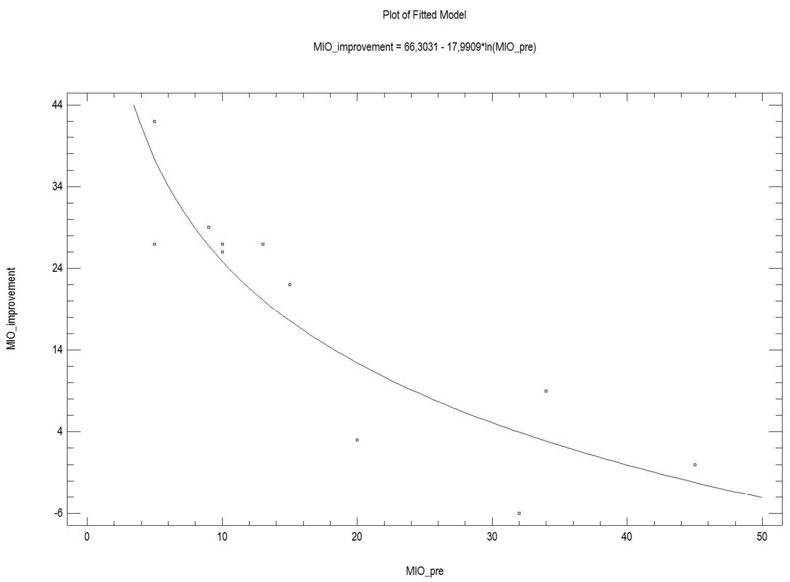
Figure 5.The relationship between maximal interincisal opening before treatment (MIO_pre) and final improvement of mouth opening (MIO_improvement – i.e. subtracting MIO_pre from MIO_post). The worse the preoperational MIO, the better the improvement.

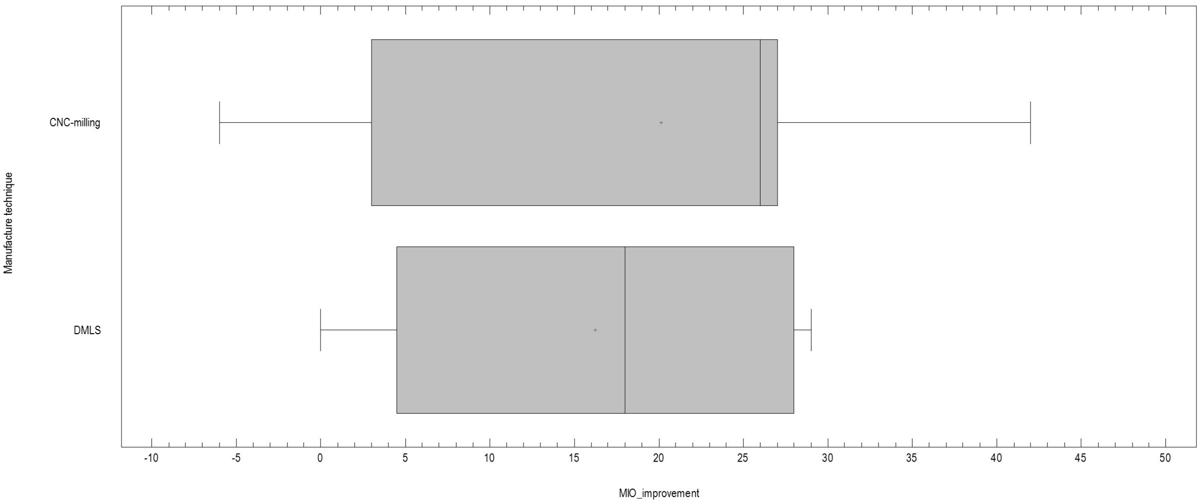
There is no conflict of interest

No	Sex	Age (years)	Diagnosis	Manufacture technique	Side	MIO_pre (mm)	Radiation therapy	MIO_post (mm)	Follow-up (months)
1	Male	47	Benign	CNC-milling	Left	5	No	47	56
2	Male	78	Benign	DMLS	Right	45	No	45	47
3	Male	74	Malignancy	CNC-milling	Left	20	Adjuvant	23	38
4	Male	25	Benign	CNC-milling	Left	13	No	40	37
5	Male	67	Malignancy	CNC-milling	Left	10	Adjuvant	37	31
6	Female	54	Malignancy	DMLS	Right	9	No	38	26
7	Male	41	Benign	CNC-milling	Right	32	No	26	5
8	Female	59	Benign	DMLS	Right	34	No	43	5
9	Male	50	Benign	CNC-milling	Left	15	No	37	32
10	Female	42	Benign	CNC-milling	Left	10	No	36	14
11	Female	57	Malignacy	DMLS	right	5	Adjuvant	32	4




CT scan
DICOM 12-bit image
Performing 3D shape of bone using MIMICS
Verification of the bone surface using Geomagic Control
Repairing defects using Geomagic Studio 14
Exporting 3D surface bone data as the .3ds file
Designing condylar and acetabular implants using mirror technique
Designing places for the implant fixation and hole for the screws-surgical templates
Approving the final virtual implant by maxilla-facial surgeon
CNC milling technique
Importing file to the EdgeCAM program
Selecting the type of tools and milling strategy
Applying cutters: first 4mm than 2mm,1mm and finaly 0.5mm. 16000 RPS with air colling or lower: 4000-6000 RPS with liquid cooling
Cleaning implants and thermally rounding the milled UHMW-PE implant
Polishing and sandblasting the titanium implant
DMLS technique
Convering the data to .stl format
Performing the division into layer using AutoFab
Dosing device sets the quantity of powder
Melting powder using focused laser beam
END OF SINTERING
Moving steel platform and sintered element to the thermal processing
Annealing for 1 hour in 700°C
Slow cooling down
Moving element to the tempering process
Automatic and manual polishing and sandblasting
Ultrasonic cleaning the implant
Marking the parts
Sterylization of the implant


Plot of Fitted Model
MIO_improvement = 66,3031 - 17,9909*ln(MIO_pre)
44
34
24
14
4
-6
MIO_improvement
0
10
20
30
40
50
MIO_pre


CNC-milling
DMLS
Manufacture technique
-10
-5
0
5
10
15
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25
30
35
40
45
50
MIO_improvement