Analyzing the Surface Finish of Knee Implants to Determine Criteria for Applications in Direct Metal Laser Sintering

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Abstract

Direct metal laser sintering (DMLS) is a relatively new additive manufacturing technology that has the potential to decrease processing time and allow for more customization. For this reason, DMLS would be useful for applications in the field of knee prosthesis. However, before DMLS components may be placed in the body, many requirements must be met for the implant to be considered safe and have long functionality in the body. One important aspect is surface roughness, which helps determine how well the components will osseointegrate with the bones in the body. The focus of this research was to determine the surface requirements of an established knee implant, which will be used as the criteria that DMLS must achieve for applications in this field. To determine the surface roughness values: $R_a$, $R_q$, and $R_z$, a profilometer was used on components of the knee implant and a DMLS tensile bar to make a comparison. The results showed that the DMLS part did not meet the roughest and smoothest surface requirements that were shown in the implant. According to this research, DMLS is not ready for applications in this field. However, the results in this research will allow DMLS to know the parameters needed to achieve this goal in future. Further investigations could be to test DMLS biocompatible materials and to see the effect of changing machine parameters on surface finish.

Keywords: Direct Metal Laser Sintering (DMLS), Knee Implants, Surface Finish

1. Introduction

The goal of this research is to analyze the surface of knee implants to determine the criteria that direct laser metal sintering (DMLS) must achieve for biomedical applications in the field of prosthesis. DMLS machines have the capability to make several physical metallic models directly from computer-aided design (CAD) models in a short time period, and doing so layer upon layer. If DMLS technology will be able to meet the surface analysis requirements, this technology would be one step closer to help optimize the fabrication of knee implants. Currently methods in which they are fabricated involve subtractive methodologies, such as forging, turning, and milling. These methods require a numerous combination of processes, especially for this field where custom-fit applications may be required. In the future, DMLS could potentially allow more customization with less processing time. In this research, the surface roughness of knee implant components were found and then compared to the surface of DMLS...
components. The surface roughness values of the established knee implant served as a baseline that DMLS must achieve in order to meet these criteria to be considered for implantation.

1.1. Knee Arthroplasty

Knee arthroplasty is the surgical procedure that replaces damaged bone and cartilage of the knee joint with metal alloys that attempt to replicate the knee’s natural abilities. In the United States, approximately 581,000 people receive knee replacement surgery per year. 90% of people who undergo total knee replacement feel a large reduction in pain and increase in their ability to perform everyday activities. The knee is the largest joint in the body and is made up of the femur, tibia, and patella. These three bones are touching at the articular cartilage, which cushions the bones to facilitate movements. Generally, all the components of the knee work well in conjunction with one another, but injuries and wearing of the knee can cause pain and reduced function.

1.2. Biomaterials

Before any implant can be placed in the body, many requirements must be met for the biomaterials involved; otherwise, the long-term usage can cause many adverse affects in the body. The requirement for biomaterials are that they must have long fatigue life, high corrosion resistance, low wear resistance, biocompatibility, and be able to osseointegrate with bone. Without these properties, there is the possibility of causing harm to the body and having revision surgeries. This research focuses specifically on idea of osseointegration, the process of formation of new bone and bone healing. When an implant is unable to join with adjacent bones and other tissues, it causes loosening of the implant. The cause of this is due to improper surface roughness, which is where the application of this research lies.

For this research, the knee implant fabricated by Non-Ferrous materials Technology Development Centre (NFTDC), shown in Figure 1, uses only biomaterials that fit all the criteria stated above; therefore, only three types of material were used to create this implant: Cobalt-Chrome-Molybdenum (Co-Cr-Mo ASTM 75), Titanium-6-Al-4, and ultra-high molecular-weight polyethylene (UHMWPE). Cobalt-Chrome-Molybdenum, more commonly known as Co-Cr, fits the requirements because it has high corrosion resistance, resistance to fatigue and crack, and most importantly the ability to achieve really smooth surface finish. Titanium-64 has high strength and high resistance to corrosion. Most importantly it is able to achieve the surface roughness requirements to become tightly integrated to the bone. The other material used is UHMWPE, which is a good biocompatible thermoplastic polyethylene. Table 1 details the various components of the knee implant along with the material used to manufacture them.

![Figure 1. NFTDC Established Knee Implant](image)
1.3. Subtractive Manufacturing

Current methods of making knee implants are done mainly using subtractive manufacturing methods. In this method, machine tools are used to cut and subtract material to achieve the desired geometry. Two major categories of machine processing that are of importance to this research are milling and turning. Milling is where the workplace is moved radially against a milling cutter. Turning is the process where a single point cutting tool is parallel to the surface. Other processes that are involved with implants include forging, which is a flow process where there is neither a removal nor addition process. Forging is the shaping of metal using localized compressive forces. For the knee implants established by NFTDC, the main methods of fabrication were turning, milling, and forging.

1.4. Additive Manufacturing

Additive manufacturing (AM) is a manufacturing process of joining materials to fabricate objects from 3-D model data, usually layer upon layer, as opposed to subtractive methodologies. Rapid prototyping (RP) is an earlier name for AM employed for the fabrication of 3-D prototypes, which are used as visualization and inspection tools. RP machines have the capability to make several physical models directly from computer-aided design (CAD) models in a short time span, and doing so layer upon layer. The fabrication of polymer prototypes is already very well established in the market. However, AM research is looking to improve on a relatively new additive technology that involves metal fabrication, using DMLS machines.

In DMLS technique, the solid metal model is made layer by layer (Figure 2). A powder comprising of metal alloys is processed by a Yb-fiber laser is in an inert and thermally controlled environment. A scanning mirror controls the laser that describes the geometry of the layer on the surface of the material. The particles of the material are heated to the point where it is sintered. It is then joined with the previous layer. Once the material solidifies for that layer, a new layer of powder is added and the laser scans that new layer again. The benefit of using AM for applications in implants is the ease of customization since the parts are made from CAD models. DMLS also allows for fewer processes to achieve one part, which would be more cost effective for custom-fit applications.

Table 1. Label of Components in Figure 1

<table>
<thead>
<tr>
<th>Label No.</th>
<th>Name of Part</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Tibial Stem</td>
<td>Ti-64</td>
</tr>
<tr>
<td>2</td>
<td>Tibial Tray</td>
<td>Ti-64</td>
</tr>
<tr>
<td>3</td>
<td>Tibial Poly</td>
<td>UHMWPE</td>
</tr>
<tr>
<td>4</td>
<td>Femoral Condyle</td>
<td>Co-Cr</td>
</tr>
<tr>
<td>5</td>
<td>Femoral Extension Piece</td>
<td>Ti-64</td>
</tr>
<tr>
<td>6</td>
<td>Femoral Collar</td>
<td>Ti-64</td>
</tr>
<tr>
<td>7</td>
<td>Femoral Stem</td>
<td>Ti-64</td>
</tr>
<tr>
<td>8</td>
<td>Central Pin</td>
<td>Co-Cr</td>
</tr>
<tr>
<td>9</td>
<td>Condylar Bushes</td>
<td>UHMWPE</td>
</tr>
</tbody>
</table>
1.5. Surface Roughness

Surface roughness is quantified by vertical deviations from an ideal surface. The importance of surface roughness for biomedical implants is the bone-bonding ability, which ultimately influences its performance and function. With implants, there are areas of the implant where it is important for the bone to integrate with it, such as, the femoral and tibial stems of a knee implant, (See Table 1) which are placed into the bone and is the main site for implant-to-bone integration. There are also components of the implant where tissue should not integrate, such as, the femoral condyle (See Table 1), which has the patella directly over it. The patella needs to slide back and forth across it in order for movement to occur; therefore, it must not bond with the condyle. Since bone-bonding ability greatly increases with increase in surface roughness values, the femoral and tibial stems would have the roughest surfaces and the femoral condyle will have the smoothest. DMLS will need to reproduce components that are able to achieve these two extremes in order for it to be placed in the body. The cells responsible for bone growth are osteoblast, which are the cells responsible for bone formation. These cells are approximately 10 µm and for continual viability of bone ingrowth, the pore space must be greater than 75 um in diameter, which attributes to a large surface roughness value.

The values that are looked at are the arithmetic average (Ra), Root Mean Square (Rq), and Ten-Point Mean Roughness (Rz). Ra is the absolute departure of the profile from the reference line throughout sampling length. This is an easy-to-acquire and standard value to give a general idea of surface roughness, but does not give any information regarding any irregularities between peaks and valleys, in a profile.

\[ R_a = \frac{1}{n} \sum_{i=1}^{n} |y_i| \]  

(1)

Rq is another method for averaging data, but obtained by squaring and then taking the square root of mean values. This value is considered a more statistically effective tool and better measure of the actual effect of the surface than Ra.

\[ R_q = \sqrt{\frac{1}{n} \sum_{i=1}^{n} y_i^2} \]  

(2)

Rz is the average distance between the maximum peaks (Rp) and minimum valleys (Rv) in each sampling length. This value is used in biomedical applications because it tells more about the overall surface quality because it takes values from the extremes values.
The $R_a$, $R_q$, and $R_z$ values are affected by the machining process in which the material undergoes. Surface roughness is also affected by lay patterns, which are the measure of the direction of the predominant machining pattern. To obtain the maximum $R_a$, $R_q$, and $R_z$ values of a surface, the measurement traces are taken perpendicular to the direction of lay. To attain the minimum values, the trace is taken parallel to the direction of lay.

2. Methodology

The objective of this research was to analyze the surface of knee implants to determine the criteria that direct laser metal sintering (DMLS) must achieve for biomedical applications. In order to form these criteria, a knee implant with an established surface roughness that works according to clinical trials conducted by NFTDC was analyzed.

2.1. Established Surface Roughness From NFTDC Knee Implant

The surface roughness data was acquired for all components of the NFTDC knee implant through the use of a profilometer, a measuring instrument used to measure surface profile. The model used was the Taylor Hobson Form Talysurf (FTS) Intra 50, shown in Figure 3. This is a contact profilometer which uses a diamond tip stylus with an inductive gauge. The stylus read the raw profile of a surface and compiled that data into the software created by Taylor Hobson called UltraVersion. This software was then used to calculate the values needed in this research: $R_a$, $R_q$, and $R_z$.

Each component of the knee implant was analyzed at varying surfaces of that component. Each surface was analyzed perpendicular and parallel to the lay to get average $R_a$, $R_q$, and $R_z$. A comparison between the components and the DMLS tensile bar was made in terms of their surface roughness.

2.2. Analysis Of DMLS Tensile Bar

DMLS tensile bars made of Stainless Steel-17-4 from Johnson & Johnson were analyzed to roughly see the capabilities of surface finish with these machines. One side of the tensile bar was as sintered (Figure 4) and the other side of the bar was machined to take off support structures from the DMLS process. Both surfaces were tested for their surface roughness. The as-sintered side was tested parallel and perpendicular to the part. The machined side was tested parallel and perpendicular to the lay to achieve average values for $R_a$, $R_q$, and $R_z$. 

\[
R_z = \frac{1}{2} \sum_{i=1}^{n} R_{pi} - R_{qi}
\]
3. Results

The results in Table 2 and 3 show the average of $R_a$, $R_q$, and $R_z$ values of the tibial stem, femoral condyle, femoral stem, and the DMLS bar (as-sintered and machined). Surface roughness values of all components in the knee implant (see Figure 1) were determined. However, the analysis for this research focused on only these three implant components because the stems of the implant exhibit the largest roughness since these components interact directly into the bone and the condyle exhibits the smoothest surface finish since it must not integrate with tissue. These values from the extremes (stem components and condyle) are looked at as the criteria needed for comparison to the DMLS components.

Table 2: Average $R_a$, $R_q$, and $R_z$ Values in Direction of Lay for Tibial Stem, Femoral Condyle, and Femoral Stem

<table>
<thead>
<tr>
<th>Component</th>
<th>Average $R_a$ [$\mu$m]</th>
<th>Average $R_q$ [$\mu$m]</th>
<th>Average $R_z$ [$\mu$m]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Parallel</td>
<td>Perpendicular</td>
<td>Parallel</td>
</tr>
<tr>
<td>Tibial Stem</td>
<td>-</td>
<td>1.8149</td>
<td>-</td>
</tr>
<tr>
<td>Femoral Condyle</td>
<td>0.0723</td>
<td>0.3177</td>
<td>0.1245</td>
</tr>
<tr>
<td>Femoral Stem</td>
<td>-</td>
<td>1.1745</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 3: Average $R_a$, $R_q$, and $R_z$ Values for DMLS Tensile Bar As-sintered and Machined

<table>
<thead>
<tr>
<th>DMLS Bar Surface Finish</th>
<th>$R_a$ [$\mu$m]</th>
<th>$R_q$ [$\mu$m]</th>
<th>$R_z$ [$\mu$m]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Parallel</td>
<td>Perpendicular</td>
<td>Parallel</td>
</tr>
<tr>
<td>As-sintered</td>
<td>-</td>
<td>0.8708</td>
<td>-</td>
</tr>
<tr>
<td>Machined</td>
<td>0.2751</td>
<td>1.2954</td>
<td>0.3991</td>
</tr>
</tbody>
</table>
Figure 5: Comparison between $R_a$, $R_q$, and $R_z$ Values Perpendicular to Lay Between Tibial Stem, DMLS Bar (Machined), DMLS Bar (As-sintered), and Femoral Condyle

Figure 5 shows the comparison between $R_a$, $R_q$, and $R_z$ values perpendicular to lay between tibial stem, DMLS Bar (machined), DMLS bar (as-sintered), and femoral condyle. Only the values for perpendicular to the lay were looked at, since the stems were circular and the tip of the profilometer did not have enough distance to move horizontally parallel to the lay. When looking at the bar graph, it shows that the DMLS tensile bar as-sintered and the machined side do not meet the smoothness required of the femoral condyle or the roughness of the tibial stem for $R_a$, $R_q$, or $R_z$.

4. Limitations/Further Research

Limitations with this research was due to the inability to acquire samples of a biocompatible material made from a DMLS machine, which would have allowed for better comparison to the components of the knee implant. Only available materials made through DMLS were Stainless Steel-17-4, which are not biocompatible. Since characteristics of the part depend on the material in which it is made, further studies that compare biocompatible DMLS parts made of materials like Ti-64 and Co-Cr-Mo with parts made by traditional processes, would allow for a better comparison on surface roughness. In addition, a study on how finely polished that material can be could also be done. The post-processing time can be compared to the time it takes to machine the same component to see if DMLS requires less processing time. Further research that can be done is through testing variable parameters of the DMLS machine to see the effect on surface finish. Some variable parameters could be scan spacing, layer thickness, laser power, scan speed, chamber temperature and laser diameter. Post-processing techniques can also be studied to see if the required surface finish can be achieved.

5. Conclusion

The goal of this research is to analyze the surface of knee implants to determine the criteria that DMLS must achieve for applications in biomedical implants. According to results of this research, the DMLS parts did not show values at the required smoothest roughness in the implant or the roughest requirements, when coming directly off the machine with minimal post-processing. The analysis of the surface roughness in this research should allow the DMLS technology to have a greater understanding of the wide range of surface finishes needed in implant applications. With further investigations in varying machine parameters and post-processing methods, DMLS has a great potential to optimize the fabrication of biomedical implants in the future.
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8. References

2. Interview with Nagsen Phule.
5. Interview with Nitin Kanoongo.