5

MACHINING APPLICATIONS

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5.1 INTRODUCTION

Metals have been the primary materials in the past for machining applications due to their superior mechanical properties. Metallic biomedical implants work under complex mechanical load in a salty environment, and it demands a high corrosion resistance of the material. Corrosion of the implants may release particles or metallic ions in the body and cause premature implant failure; besides, adverse reactions may occur. Biocompatible metal materials (biometals) such as stainless steel, cobalt-chromium-molybdenum alloys, titanium, and titanium-nickel alloys have been used [1, 2] in orthopedic implants, fixation systems, and many other medical implants with several applications (see Table 5.1 and Figure 5.1).

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TABLE 5.1 Medical Implants and Alloy Materials Used

Medical Field	Implant Type	Alloy Material
Cardiovascular	Stents and valves	SS-316L; Co-Cr-Mo; Ti, Ti-6Al-4V
Craniofacial	Plates and screws	316L SS; CoCrMo; Ti; Ti6Al4V
Dental	Orthodontic wires	SS-316L; Co-Cr-Mo; Ni-Ti; Ti-Mo
Orthopedic	Joint replacements	SS-316L; Ti; Ti-6Al-4V; Ti-6Al-7Nb; Co-Cr-Mo
Spinal	Fixation plates, screws, pins	SS-316L; Ti; Ti-6Al-4V

(a) (b)

Figure 5.1 (a) Titanium alloy Ti-6Al-4V spinal fixation plate and (b) SS316L stainless steel bone crusher as produced with micromilling.

Biometals used in orthopedic implants mainly include surgical-grade stainless steel, cobalt-chromium alloys, titanium and nickel-titanium alloys, among others.

In general, stainless steel is not suitable for a permanent implant because of its poor fatigue strength, its liability to undergo plastic deformation, and poor corrosion resistance. For this reason, stainless steel is used only for nonpermanent implants such as internal fixation devices for fractures. Most commonly, permanent implants are made of cobalt-based alloys (Co-Cr-Mo and Co-Cr-Ni) or Ti alloys. These alloys are more corrosion resistant; particularly, Co alloys generate a durable chromium-oxide surface layer (so-called passivation layer). Despite good corrosion resistance, chromium and nickel are known as carcinogens; in addition, their elastic modulus (221 GPa) is roughly 10 times the stiffness of cortical bone. It is necessary to consider that the regenerative and remodeling processes in bones are directly triggered by loading; that is, bone subjected to loading or stress regenerates and bone not subjected to loading results in atrophy. Thus, the effect of a much stiffer bone implant is to reduce the loading on bone resulting in the phenomenon called "stress shielding." This phenomenon can lead to resorption of the bone and to the loss of the implant. Those findings have led to the use of titanium alloy for prosthetic devices (specifically for cemented ones).

Titanium alloys are preferred typically for medical implants because of light weight, high strength, and biocompatibility. Also, titanium implants are compatible

with magnetic resonance imaging and computed tomography imaging procedures; therefore, they do not interfere with the procedures if the patient needs them after the implant is made. Titanium and its alloys have also been demonstrated to be more corrosion resistant than cobalt-chrome alloys because of the formation of titanium oxide, which is in fact a ceramic, on the surface. Moreover, these metals have been considered to be the most biocompatible among metal materials. However, titanium does bond directly to bone, which can result in the loosening of the implant. One approach to improving implant lifetime is to coat the metal surface with a bioactive material that can promote the formation and adhesion of hydroxyapatite, the inorganic component of natural bone. Bioglass coatings on Ti implants further improve the biocompatibility of these implants [3].

The glasses are based on mixtures of the oxides of silicon, sodium, potassium, calcium, and magnesium. Also, the glasses become soft at the processing temperature, which is well below the melting point of the Ti alloy. Thus, they flow to uniformly coat the Ti surface. These coatings develop a layer of hydroxyapatite on their outer surface upon exposure to simulated body fluid. Another important issue connected with the use of metal materials in implant generation is the dangerous particles that result from wear debris. Also, in this case, it has been verified that a bioglass coating can reduce the problem.

Some of the specific mechanical properties of the alloys used in joint replacements and their microstructure are summarized in Table 5.2 [2, 4].

Pure titanium and Ti-6Al-4V are the main materials used in the dental field and in the surgical field. Ti-6Al-7Nb, which has been developed for surgical implants, is also attractive for dental applications.

TABLE 5.2 Mechanical Properties of Alloys Used in Joint Replacements

Alloy Material	Microstructure	Tensile Strength (MPa)	Modulus (GPa)
Ti (pure titanium)	{α}	785	105
Ti-Zr	Cast {α′/β}	900	1
Co-Cr alloys		655–1896	0.9–253
Co-Cr-Mo	{Austenite (fcc) + hcp}	600–1795	8.3–230
Ti-6Al-4V	{α′/β}	960–970	0.4
Ti-6Al-7Nb	{α/β}	1024	105
Ti-5Al-2.5Fe	{α/β}	1033	110
Ti-13Nb-13Zr	{α′/β}	1030	79
Ti-15Mo-5Zr-3Al	{Metastable β}	882–975	75
Ti-12Mo-6Zr-2Fe	{Metastable β}	1060–1100	74–85
Ti-15Mo-5Zr-3Al	{Metastable β}	882–975	75
SS-316L	{Austenite}	465–950	200
Ti-15Mo-2.8Nb-3Al	{Metastable β}	812	82
Ti-35Nb-5Ta-7Zr	{Metastable β}	590	55
Ti-35Nb-5Ta-7Zr-0.4O (TNZTO)	{Metastable β}	1010	66

TABLE 5.3 Biocompatibility of Biomaterials Including Metal Alloys

Biomaterial	Patterns	Biocompatibility
Stainless steel, Co–Cr alloy, titanium, titanium alloys	Intervend osteogenesis Contact osteogenesis	Biotolerant materials Bioinert materials
Bonding osteogenesis	Bioglass, Ceravital tricalcium phosphate, hydroxyapatite	Bioactive materials

Titanium alloys show the greatest biocompatibility among metallic materials for biomedical applications (see Table 5.3). However, they are grouped into bioinert materials as well as ceramics such as alumina and zirconia, judging from the pattern of osteogenesis as stated earlier, and its biocompatibility is inferior to that of phosphate calcium or hydroxyapatite, which is grouped into bioactive materials. Therefore, bioactive surface treatment (bioactive surface modification) is in general applied to titanium alloys for biomedical applications in order to improve their biocompatibility [3, 5].

5.2 MACHINABILITY OF BIOCOMPATIBLE METAL ALLOYS

Orthopedic devices are designed to conform to the complex shape of bones and joints; therefore, the machining of these parts is also complex. Devices machined from bar stock require a lot of material to be removed, resulting in an expensive process because of the low machinability rating of many of the materials involved. As a result, some parts are cast to near net shape, which often requires fixturing that is complex and expensive. Another issue that adds to the complexity of machining is the tight tolerances required—50 μm or less for most devices.

Machinability of biocompatible metal alloys, such as stainless steel, titanium alloys, and titanium-nickel alloys, is considered highly difficult due to their low thermal conductivity and diffusivity, high rigidity and low elasticity modulus, and high chemical reactivity at elevated temperatures; and resultant machining-induced surface quality and structural surface integrity may not be acceptable at the readiness levels suitable for biomedical applications as reviewed in the literature by several peer research groups [6, 7].

As a group of shape memory alloy with ample biomedical applications, the nickel-titanium alloys based on nitinol (Ni-Ti) is also widely used because of their shape memory-based actuating property that can be employed in catheters, forceps, biopsy, and surgical devices. Machining these alloys was found to be very difficult, owing to their high ductility and work-hardening behavior [8]. Weinert and Petzoldt suggested that for these materials, the tool wear is high whether the feed rate and cutting speed are high or low; therefore, increasing the material removal rate while taking care of the surface quality by rapid tool changing was recommended. Micromilling was proposed as a favorable method to machine these materials, and using a minimum quantity of lubrication was suggested for

increased surface quality [9]. Micromilling at a cutting speed of 33 m/min, feeds of 6–30 μm/tooth, depths of cut of 10–100 μm, and a width of cut of 250 μm, a high feed rate, and a relatively high width of cut was found to form better chips, which extended tool life and enhanced the workpiece quality. In addition to minimum quantity lubrication, tool coating was suggested rather than using uncoated tools, but multilayer TiCN/TiAlN- or TiCN/TiN-coated cemented carbide tools were found to provide better results compared with PCD or CBN tools in turning and drilling processes in terms of workpiece quality and tool costs [7].

Once machining induced properties are controlled, these types of biocompatible metallic materials can be extremely useful for the biomedical industry, because of their improved surface quality and surface integrity properties. They can be used in biomedical devices such as stents, dental implants, orthopedic implants, and other devices, and their high biocompatibility with the human body is a significant concern.

The surface integrity of the final biomedical part is highly crucial in machining processes. In most applications, having the smoothest possible surface is desired, especially when strength under static loading and fatigue life of a medical device component is important. However, in some cases, having a rougher surface can be preferred typically in some medical device applications or in the biomedical field generally.

Machining processes induce and affect various surface integrity attributes on the finished parts [7]. These can be grouped as (1) topography characteristics such as textures, waviness, and surface roughness, (2) mechanical properties affected such as residual stresses and hardness, and (3) metallurgical state such as microstructure, phase transformation, grain size and shape, inclusions, etc. These alterations of surface are considered in five groups: mechanical, thermal, metallurgical, chemical, and electrical properties.

Machining can cause many defects on the surfaces produced since it is a material removal process. Main forms of defects are surface drag, material pull-out/cracking, feed marks, adhered material particles, tearing surface, chip layer formation, debris of microchips, surface plucking, deformed grains, surface cavities, slip zones, laps (material folded onto the surface), and lay patterns [7].

The cutting parameters can affect these defects to some degree, which need to be controlled. Feed marks are effective in machining, but their severity can be altered by varying and optimizing the feed rate. Cutting speed values can affect the amount of microchip debris on the surface, and material plucking, tearing, dragging, and smearing can be affected by depth of cut among other parameters. During machining of nickel and titanium alloys, such problems can be problematic, so optimizing the cutting conditions is essential [7].

There are many surface defects that can be found in machining processes, especially when investigated in high precision. The main surface defects are considered to be feed marks, chip redeposition to the surface, and grain deformations, since these are the ones in the biggest scale among the surface defects. Also, plucking of particles from the surface and their redeposition to the surface create two different defects, whereas these particles can also cause dragging and tearing defects on the next pass

from the surface. Adjusting cutting parameters according to these defects is very hard, and even then, a complete elimination is not possible [7].

Many workpiece materials include carbide particles in their structure. Also, many coating materials involve some carbide in them. As the tool wears, and the workpiece is machined, these carbide particles are sometimes removed from the machined surface or the tool and get stuck on the workpiece surface. This phenomenon is called carbide cracking, and it causes a sudden increase in the shear stress during cutting that leads to surface cavities due to plucking. This process causes residual cavities and cracks to be formed inside the machined surface, causing even further problems [7].

Both titanium and nickel alloys are prone to carbide cracking where the existence of crack locations decreases the fatigue life of the material substantially. These materials are strengthened by carbides such as titanium carbide and niobium carbide. When feed rates and depth of cut values lower than 50 μm are used to observe the possibility of good surface roughness, the carbide particles from these strengthening pieces were observed to crack from the surface and be smeared to another part of the workpiece material to create surface integrity problems. The sizes of these carbide particles were also found to be around 20 μm, comparable to the feed rate and depth of cut values. Carbide particles are unable to deform, which means they cannot be removed completely at once, leaving cavities behind, as well as causing high oscillations in forces. Hence, taking these possibilities into account, planning the machining processes accordingly for biomedical applications is extremely important [7].

5.3 SURFACES ENGINEERING OF METAL IMPLANTS

In particular, in the case of cobalt-chromium-molybdenum alloys, the metal-on-metal (MoM) implants show a higher wear resistance than the metal-on-polymer (MoP) ones, even if they cannot avoid the formation of wear debris. Furthermore, debris deriving from MoP implants usually generates inflammatory process with destruction of bone tissue (osteolysis), while MoM is rarely associated with osteolysis. This allows using larger diameter of the femoral heads in order to increase the stability [10].

The debris formation is mainly due to fatigue phenomenon and to high contact stresses on the surface. Under these cycles, the chromium and molybdenum carbides can be fractured, adding wear on the contact surfaces by indentation and abrasion of a third part. Thus, the generation of residual stresses of compression on the surfaces during machining could minimize the debris formation due to surface fatigue. The problem of Co-Cr-Mo alloys is that they are difficult to machine materials, since they have high work-hardening rate, low thermal conductivity, and the presence of hard abrasive carbides [11].

Usually, when the implants are under working conditions, the particular components are subjected to surface and subsurface alterations. These tribochemical effects lead to the formation of a nanocrystalline surface region that, during fatigue cycles,

cracks, and this is the main cause of debris generation. In order to improve the surface characteristics of the particular components of the implants, several studies were performed by making heat treatment and surface coating. However, the heat treatment changes the chemical structure of the whole component, while with surface coating problems of spalling and adhesion with the new layers were presented.

Various surface modification technologies relating to titanium and titanium alloys including mechanical treatment, thermal spraying, sol-gel, chemical and electrochemical treatment, and ion implantation are applied from the perspective of biomedical applications. Wear resistance, corrosion resistance, and biological properties of titanium and titanium alloys can be improved selectively using the appropriate surface treatment techniques while the desirable bulk attributes of the materials are retained [11].

Magnesium and magnesium-based alloys are lightweight metallic materials that are extremely biocompatible and have mechanical properties that are similar to natural bone. These materials have the potential to function as an osteoconductive and biodegradable substitute in load bearing applications in the field of hard tissue engineering. However, the effects of corrosion and degradation in the physiological environment of the body has prevented their widespread application to date [12].

There has been research on the methods of improving the corrosion resistance of magnesium and its alloys for potential application in the orthopedic field. To be an effective implant, the surface and subsurface properties of the material need to be carefully selected so that the degradation kinetics of the implant can be efficiently controlled. Several surface modification techniques are presented and their effectiveness in reducing the corrosion rate and methods of controlling the degradation period are discussed. Ideally, balancing the gradual loss of material and mechanical strength during degradation, with the increasing strength and stability of the newly forming bone tissue, is the ultimate goal. If these methods prove to be successful, orthopedic implants manufactured from magnesium-based alloys have the potential to deliver successful clinical outcomes without the need for revision surgery [13].

In the case of orthopedic implants made of magnesium-calcium alloys, the main problem is that the material is quickly biodegradable in the body environment. Thus, one challenge is to control the degradation rate. It was shown that the optimization of the residual stress distribution could decrease the degradation rate, and by adjusting the machining-induced surface residual stress profile, this rate can be reduced significantly [6, 7].

5.4 WEAR AND FAILURE OF METAL IMPLANTS

The joint replacement procedure involves surgical operation for removing the diseased area and replacing the joint with a prosthesis made of biocompatible metal material. Once the prostheses is implanted in the patient, several factors may affect the performance of the metal implant, such as the interaction with the human body or the mechanical loads, of static and dynamic nature, generated during the daily movements. These could lead to the failure of the metal implant and consequently to

risks for patient health. The failure modes resulting from machining processes could include high cycle fatigue cracking due to surface microcracks, wear of the surfaces in contact with relative debris formation due to undesirable subsurface quality, and bacterial annexation due to the absorption of biomolecules by the prostheses metal material that usually causes inflammation of soft and hard tissues. These modes are deeply related to the metal material utilized for the prostheses production via machining processes. For this reason, failure is one of the most important aspects of implant material behavior and directly influences the choice of metal materials and machining methods [7, 11].

In the case of temporary metal implants, such as plates and screws utilized for fixing fractured bones, the metal implant alloy needs to be bioabsorbable and biodegradable in the body environment. However, in order to permit the growth of bone tissue and make the tissue growth stable, the metal implant material should not be highly degradable during the bone development period, where the stability of the temporary implant and of the bone tissue is reported as a function of the time after the implantation. Magnesium-calcium alloys are usually used for this purpose. The failure related to this type of alloy is the rapid biodegradation when they are placed in the human body. This could result in incomplete bone formation before the complete absorption of the implants, with a catastrophic breakage due to the poor stability of the new bone tissue. This problem could be solved by controlling the biodegradation rate and avoiding the absorption of the implant, by realizing the final parts with specific surface characteristics [12].

When metallic permanent joint prostheses are considered, the materials constituting all the parts are not biodegradable. In this case, the main causes of failure are high cycle fatigue, corrosion under stress phenomena, wear and debris formation. The failure under high cycle fatigue is usually related to a wrong prostheses design. In such case, under torsional and bending momentum, a high stress concentration area could occur, leading to a premature cracking of the implant. The high level contact stresses generated between the implant parts, during the running, should cause the beginning of corrosion phenomenon [12].

When the wear particles are produced, they generate micro-cutting and micro-ploughing phenomena due to abrasions that lead to the formation of scratches and grooves on the surfaces. Moreover, agglomeration, compaction, and cold sintering of debris, due to high contact stresses and sliding conditions, generate adhesive wear.

Since the failure of metallic implants are mainly related to wear and debris formation, which are heavily affected by the surface integrity, it results in great interest to find a correlation between the surface characteristics and growing wear [12].

5.5 MICROMILLING-BASED FABRICATION OF METALLIC MICROCHANNELS FOR MEDICAL DEVICES

Special medical devices for microfluidic applications such as lab-on-chip (LOC), micropump, microvalves, and microthermal devices are diffused in the medical field.

In particular, the LOC is a device integrating functions of several laboratories (sample pretreatment, cleaning, and separation) on a single chip. An LOC is composed by channels with different sizes and geometries, accurately designed for handling a very small fluid volume (less than picoliters). DNA analysis, enzymatic analysis, and clinical pathology are some of the application areas of LOC. The main advantages introduced by LOC are the cost reduction, the low consumption of fluid and the faster analysis and response times.

Different manufacturing processes can be used for realizing the microchannels on the chip, amongst them photolithography, etching, additive manufacturing, laser, electroplating, embossing and, recently, machining, that is, micromilling. Although these micro-manufacturing processes allow obtaining features characterized by high geometrical accuracy, precision, and low surface roughness, often they are not able to guarantee the needed precision when microscale is considered. In terms of machining-related issues, quality of channels geometry, precision of channel dimensions, burrs at the edges of the channels, and surface roughness at the bottom and side walls are some of the aspects to be considered for having good quality analyses [14].

The Micromilling process is one of the mechanical micromachining processes. It is a scale-down version of the conventional end milling process. Micro-end-milling is typically used to produce miniature parts that are not axially symmetric and have many features, such as holes, slots, pockets, and even three-dimensional surface contours. Micromilling is still a tool-based material removal process; hence, it very much relies on the performance of the micromilling tools. Also, this happens to be a barrier limiting the capability of mechanical micromachining. This problem is encountered when scaling down the tool; there are some features of the tool that cannot be reduced further. This problem affects one of the most critical tool geometry, the edge radius. A limitation of grinding technology, grain size, and edge strength limits further reduction of the edge radius. Inevitably, the microtools are normally fabricated with an edge radius of 1–5 μm [14–18]. When considering micromilling as the manufacturing process, these aspects are strongly affected by the process parameters (depth of cut, lubrication type, feed per tooth) [9, 14, 15], tool material and coating [15], and material microstructure [16]. As a consequence, it is very important to know how to select and optimize these process parameters for achieving the product quality requirements [17, 18].

The channel geometries and dimensions fabricated with micromilling are strongly influenced by the depth of cut. This is related to the high forces generated during the process that deflect the tool causing evident geometrical errors or deflected geometries [14, 15, 18]. The coolant factor has the highest influence on surface finish. Wet cutting considerably reduces the roughness in the floor of the channel. Moreover, an improvement in the burr reduction can be achieved when using coolant [14]. The roughness in the floor of the channel is also affected by the feed per tooth values. As in conventional slot milling operation, high feed values generate worst surface finishing. It is well known that also the material microstructure affects the final part quality, tool wear, and cutting force [16].

Ti-6Al-4V alloy can show different microstructures depending on recrystallization annealing time and temperature: bimodal (duplex) microstructure, containing equiaxed primary α in a lamellar $\alpha+\beta$ matrix, which has an excellent combination of mechanical properties; fully lamellar microstructure, having high toughness but low ductility; fully equiaxed microstructure, with fairly good strength and ductility; mill annealed microstructure, which is the result of cooling after plastic deformation, without any recrystallization annealing [16, 19].

There are several responses that are used to evaluate the process performance of micro-end-milling. Among them, burr formation, surface roughness, tool wear, cutting force, and cutting temperature are the key responses determining the success of the process. Especially, burr formation and surface roughness are directly related to the satisfactory level of quality produced [9, 15–18].

Burr is an undesirable projection part of a workpiece, which is produced through manufacturing processes on an edge or a surface that lies outside the desired geometry. Even though burr is not desirable, it is unavoidable. The only solution is to reduce it to an acceptable degree in which a machined part can function properly. Burr in end-milling can be categorized by the position where it occurs. Burr formation mechanism is very complicated involving plastic and elastic deformations, which are influenced by material properties, tool geometry, and machining parameters. Burr in micro-end-milling of metal alloys such as titanium alloy can be relatively large compared with the feature size as shown in Figure 5.2. Typically, burrs are more pronounced when the down-milling cycle is more effective than the up-milling cycle on the walls of the microchannels. It is also shown that the increasing wear of micromilling tools affect the increase of the burrs at the exit locations of the microchannels [15, 17, 18]. There is significant influence of

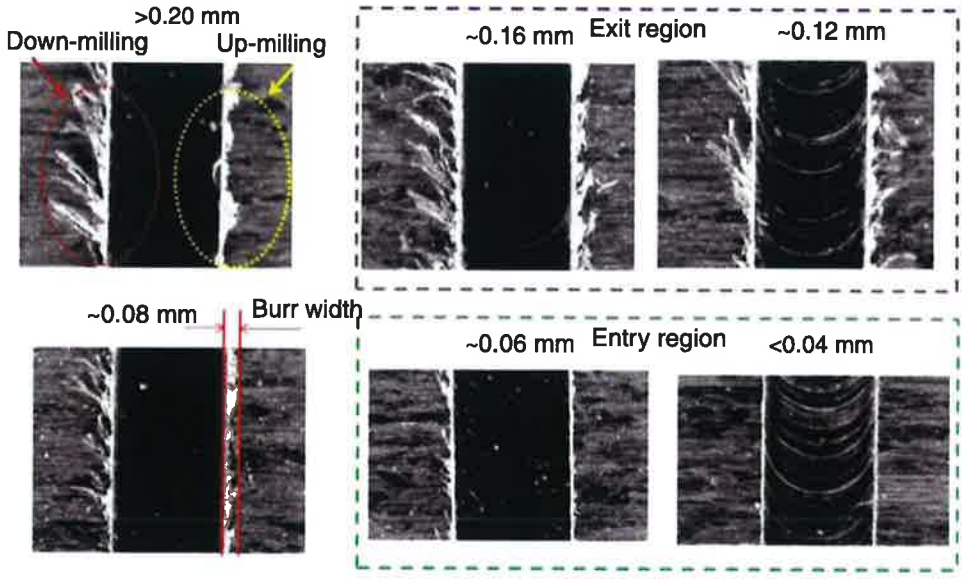


Figure 5.2 Burr formation in micromilling of channels in Ti-6Al-4V titanium alloy.

Ti-6Al-4V microstructures on burr's width and height, cutting forces, and built up edge [16]. The different behaviors are due to the different hardness and ductility of the Ti-6Al-4V microstructures. Moreover, considering only the micro-workability of this titanium alloy [19], it was demonstrated that it is strongly affected by material ductility, while hardness is a less relevant parameter [19].

The location of burr formation in medical-grade titanium alloys creates significant difficulties in terms of deburring, cleaning, and postprocessing using electropolishing, as complex features are fabricated in medical device applications (see Figure 5.2),

5.6 MACHINING-BASED FABRICATION OF POLYMERIC MICRONEEDLE DEVICES

Microneedles are innovative medical devices with the same purpose of classic hypodermic needles but fabricated on microscale often in the form of arrays in various materials. These devices aim to replace the hypodermic needles in some applications and consist of a patch with microsized needles. These microneedle array-based patches generally do not induce pain to the level of hypodermic needles since they penetrate into the skin deep enough to deliver the drug but do not reach the pain receptors. In addition, they can be applied without the help of a health-care professional, lowering the cost of delivery and improving preparedness and readiness against fighting with epidemics [20]. The basic premise of painless microneedle patches is the small individual needle size (a length of 0.5–1.5 mm and a diameter about 100–200 μm) so that each microneedle does not reach deeper than the dermis of human skin and does not agitate pain receptors but is effective in delivering the drug into the body [21]. Microneedles also offer a broad range of advantages when compared with traditional hypodermic needles [22].

Microneedle array-based patch prototypes can be developed using micromilling technology. Thepsonthi et al. [22] investigated the feasibility of directly fabricating a microneedle array-based patch prototype using micromilling of PMMA polymeric material. There are a number of design parameters for the microneedle arrays. These include a basic shape of a microneedle, the height, the base diameter (conical shape) or the base dimension (square-based pyramidal shape), horizontal and vertical spaces, and linear or circular array type. The microneedle shape is defined by considering the biomedical needs and the limitation in micromilling. The patch has to be made of biocompatible or dissolvable polymer; the needle height must be about 500 μm to 1 mm for drug storage; and the needle tips have to be sharp and penetrate easily through the skin but not fail prematurely. The micromilling process limits are related specifically to microtool sharpness and resistance of the polymeric tip during micromilling.

Due to their low thermal conductivity, polymers can exhibit thermal softening during micromilling; hence, a polymer that offers a high melting temperature and good strength is suitable for microneedle array fabrication using micromilling. In addition, an air cooling system should be employed by using an air nozzle to cool down the temperature in the polymer and also blow polymeric chips and

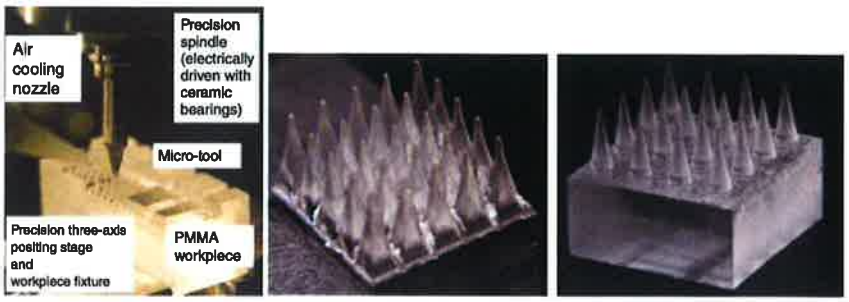


Figure 5.3 Micromilling of PMMA polymer to produce microneedle arrays. (*See color plate section for the color representation of this figure.*)

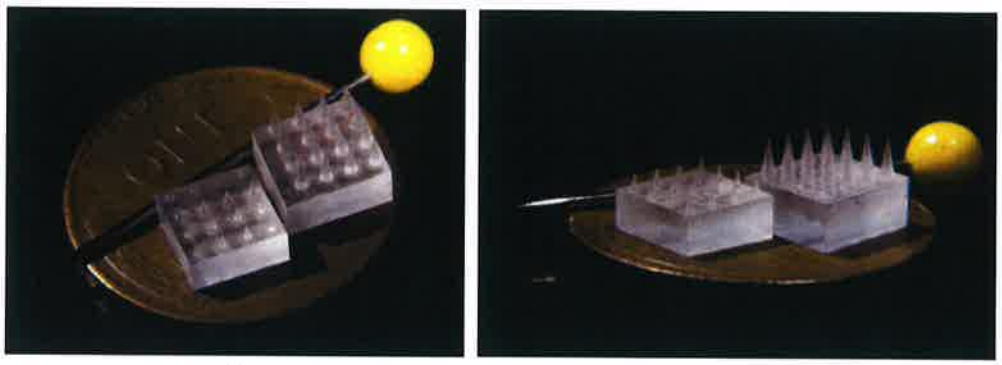
debris. Furthermore, continuous toolpaths should be designed to realize pyramidal and conical shaped microneedle arrays. Therefore, it was possible to fabricate microneedle arrays with highly sharp and burr-free tips as shown in Figure 5.3 and resultant patch prototypes as shown in Figure 5.4.

Development of microneedle arrays with various configurations such as solid, drug coated, hollow, or dissolvable type drug delivery patches using various prototyping and fabrication processes is a topic of current research studies bringing together the inter- and cross-disciplinary team of researchers from life sciences and engineering fields.

5.7 A CASE STUDY: MILLING-BASED FABRICATION OF SPINAL SPACER CAGE

The use of bioabsorbable implants in spine surgery is expanding at a rapid pace. These implants are mimicking the roles of traditional metallic devices and are demonstrating similar efficacy in terms of maintaining stability and acting as carriers for grafting substances. Biomechanical studies have demonstrated their ability to stabilize effectively a degenerative cervical and lumbar motion segment.

The objectives and assumptions of this case study are to develop the design and manufacturing of a spinal cage, starting from the material selection, product design, product finite element analysis (FEA), premanufacturing simulation and final product fabrication, to design the spinal cage which will improve the conjoint with vertebral endplate, to provide FEA for selecting better cage concerning the pattern of pyramidal teeth in superior surface. The assumptions made include the following: (i) the cage design is not specified in a certain level of cervical segment and has no concern for anterior or exterior procedures and (ii) FEA will not provide shear, flexion and extension, lateral bending, and torsion analysis; compression is the only element of concern.



(a) (b)

Figure 5.4 Microneedle array-based patch prototypes produced with micromilling.

5.7.1 Degenerative Disc Disease

Degenerative disc disease (DDD) is one of the most frequently encountered spinal disorders (Figure 5.5). Lumbar and cervical disc degeneration is commonly seen. Cross-sectional studies have shown that more than half of the middle-aged population demonstrated radiological or pathological evidence of cervical spondylosis. Cervical spondylosis is often asymptomatic; however, 10–15% of individuals have associated root or cord compression [23]. In the cervical spine, DDD can result in significant pain, instability, and radiculopathy and myelopathy. Several causes have been cited as the possible source of these symptoms, including the loss of disc space height, loss of foraminal volume, disc bulging, or protruding osteophytes causing neural compression. With regard to the lumbar spine, symptomatic disc degeneration is believed to be a common cause of chronic lower back pain [24].

At present, a wide array of treatment options, operative or nonoperative, for DDD is available. These treatments include anti-inflammatories, exercise, weight loss, physical therapy, discectomy with or without fusion, intradiscal electrothermal

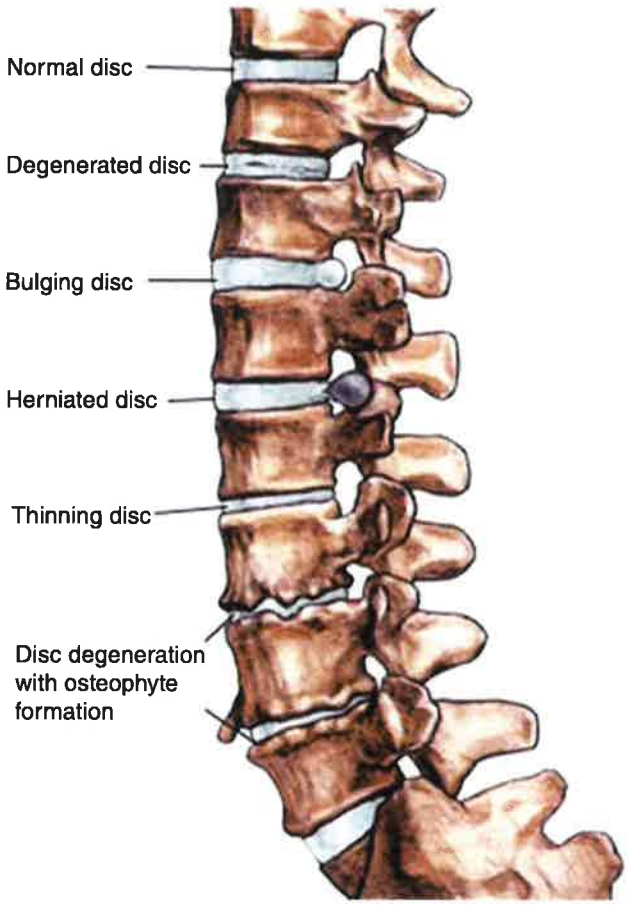


Figure 5.5 Examples of common disc problems.

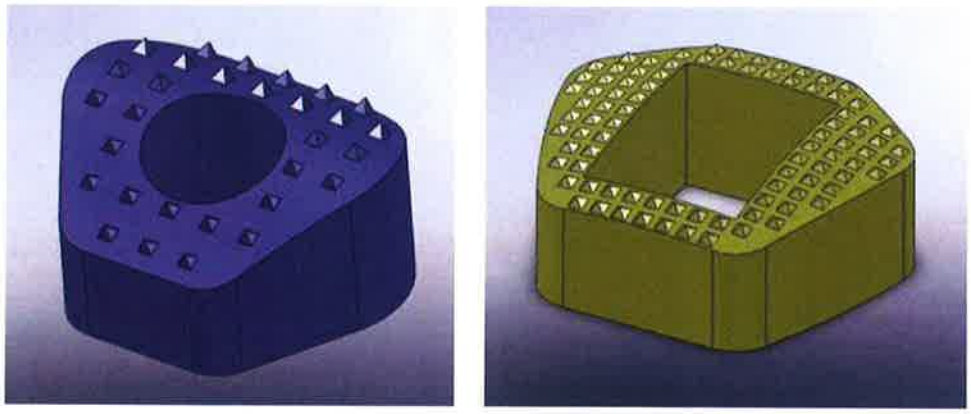
therapy, prosthetic disc nucleus device, disc arthroplasty, or bioengineered nucleus pulposus replacement [24]. However, over the past 50 years, spinal fusion has generally become the standard surgical care for numerous pathologic conditions of the spine including DDD, and typically there are two types of surgical instruments for curing degenerative fusion: (1) fixation, plates, screws, rods and (2) intervertebral spacers.

Each of them has its own characteristics, but this study focuses on the intervertebral spacers through material selection, prototype design, optimization, and fabrication.

5.7.2 Intervertebral Spinal Spacers

Different design solutions were developed by considering the following requirements: the cage has to have several sagittal profiles, a variety of heights, and specific angle implants to provide treatment flexibility; the presence of superior and inferior teeth with pyramid or serrated shape to avoid implant migration; the design of a central hole for containing autograft material. Two different spinal spacer cages were designed (as shown in Figure 5.6), with different surface method and teeth pattern method (as reported in Table 5.4).

The goal of the new design presented herein was to improve the spinal cage implants built in polymeric material, available in the market due to a several complications associated with them, such as low bone growth, migration, spine



(a) Design I (b) Design II

Figure 5.6 Spinal spacer cage designs (Rutgers Manufacturing Automation Laboratory).

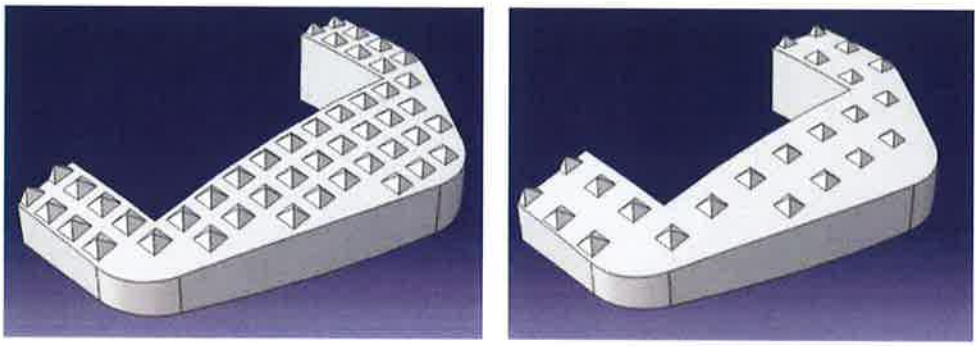
TABLE 5.4 Spinal Spacer Cage Design Methods

Part	Surface Method	Teeth Pattern Method
1	Extruded cut	Linear pattern
2	Surface sweep	Curve pattern/combine

stabilization, and soft tissue formation, among others. The new cage design was generated considering some requirements: biocompatibility/biodurability, bone fusion, spinal column stabilization, stable placement, easy insertion, customizable, radiopacity, and low cost. There are basically two types of spinal cage implants: the artificial disc and fusion product. This study was only concerning the PEEK fusion spinal cages, due to good compromise between mechanical and biocompatibility characteristics of that material and the relatively higher simplicity of fusion products [25–27].

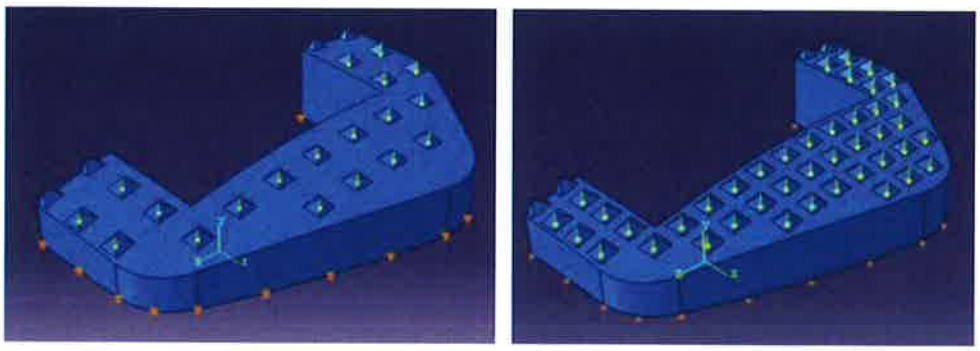
The FEA was utilized with an aim to compare two cages with different teeth densities and two different loads on each of the cages (100 N and 160 N), and to analyze the result and identify a better design. Due to the symmetry of the cage, the simulations were performed on just half models of the cage (Figure 5.7).

According to teeth density and loading, the maximum compression in the teeth was 11.9 N. Since there would be a small deformation in the top of the cage, we assume that there was no plastic deformation in this study. The bottoms of cages were set as constraints fixed in three axes during the analysis. Figure 5.8 shows the distribution of the load and constraints once the simulation was set in FEA software. The spinal cages were meshed with four-node tetrahedral mesh, as shown in Figure 5.9. Based on



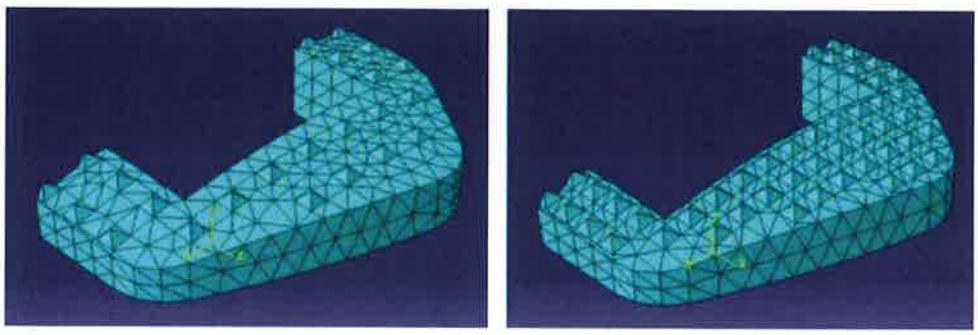
(a) Design A (b) Design B

Figure 5.7 Two design models used in finite element analysis.



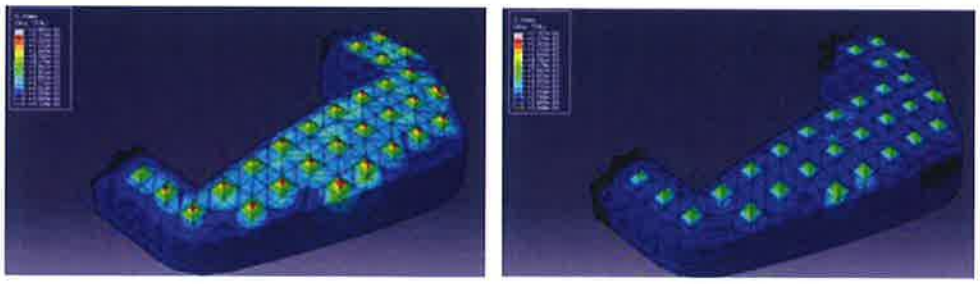
(a) Design A (b) Design B

Figure 5.8 Boundary conditions and loads for the two designs.



(a) Design A (b) Design B

Figure 5.9 Finite element mesh for the two designs (Rutgers Manufacturing Automation Laboratory).



(a) Design A (b) Design B

Figure 5.10 (a) Design A with 160 N load on 59 teeth cage and (b) Design B with 100 N load on 59 teeth cage (Rutgers Manufacturing Automation Laboratory).

the FEA, the result in Figure 5.10 shows that no deformation occurred in the design of 59 teeth cage. Therefore, we can conclude that the optimal design may be the design with the number of teeth between 42 and 59.

5.7.3 Prototype Fabrication Using Milling Process

Computer numerical control (CNC) milling process is utilized in the prototyping phase; considering the material cost, PEEK was replaced by PVC, since it has similar polymer properties. The cage size was not specified for a particular vertebrae; thus, the reasonable stock 50.75 mm × 77 mm × 50.75 mm was selected for the fabrication.

The toolpath strategies selection was critical for the prototyping purpose for several reasons. It could affect the teeth shape resulting in geometric error, rough surface, long machining time, short tool life and high cost. Figures 5.11 shows the toolpaths used in the machining simulation when a ball end mill with 0.125 in tool diameter was employed. The selection of a suitable tool not only contributes to an exquisite milling surface, but greatly enhances efficiency and reduces the cost. In addition, the proper tool selection also considers the tool loading time and machining time. In this case, a

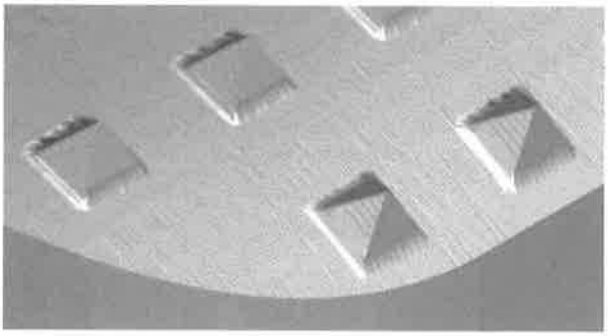


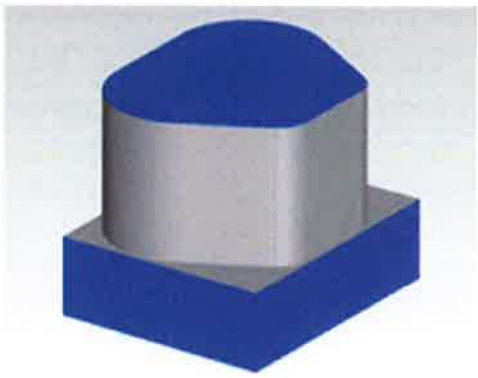
Figure 5.11 Surface obtained from the tool path strategy (Rutgers Manufacturing Automation Laboratory).

TABLE 5.5 Tools Utilized in Milling Process

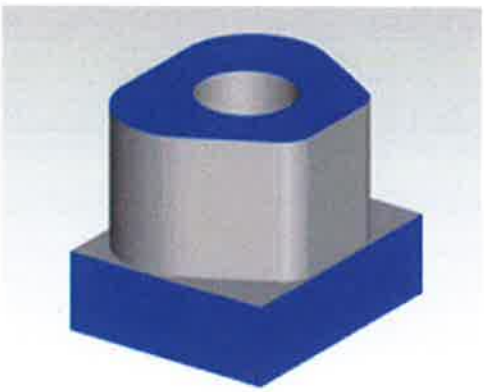
Tool Magazines		
Tool Size (in.)	Tool Type	Steps
1	End mill	Body contour lumen
0.125	Ball end mill	Rough machine for upper and bottom
0.09375	Ball end mill	Finishing machine for upper and bottom

1-in. end mill tool was utilized for the contour and lumen. Table 5.5 reports the tools adopted as a function of the different steps needed for the prototype manufacturing.

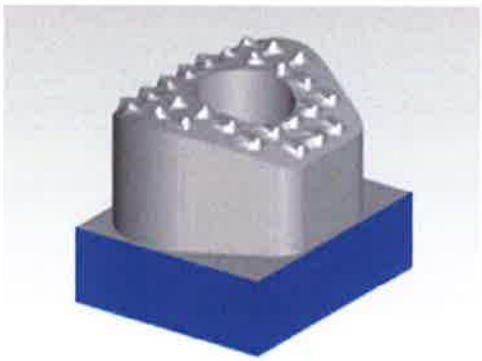
The spinal cage prototype was fabricated by a three-axis CNC machine by following the automated milling process sequence given in Figure 5.12. The first step was profile milling. This was performed on a CNC milling machine by means of a flat end mill with a diameter of 1 in. The depth of the process was 37 mm and the process parameters were a spindle speed of 2000 rpm and a feed rate of 100 mm/min. In this case, only finishing profile milling was selected, and it was due to the low hardness polymer property. The second step was hole drilling. This was also performed on a CNC milling machine by means of flat end mills with a diameter of 1 in. The depth of the process was 40 mm and the process parameters were a spindle speed of 1600 rpm and a feed rate of 800 mm/min. The hole was drilled using a peck drilling cycle to facilitate chip evacuation. The depth of the hole was 52 mm. The third step was the rough milling of the upper surface. This was performed on a CNC milling machine following the Y-parallel strategy, and by means of a two-flute ball end mill with a diameter of 0.25 in. The process parameters were a spindle speed of 2000 rpm and a feed rate of 1000 mm/min. The top part was machined with an allowance of 2 mm. Then, the finish milling of the upper surface was performed on a CNC milling machine following the toolpath strategy. The tool was a four-flute ball end mill with a diameter of 0.09375 in. The process parameters were a spindle speed of 3000 rpm and a feed rate of 300 mm/min. In order to avoid misalignment when



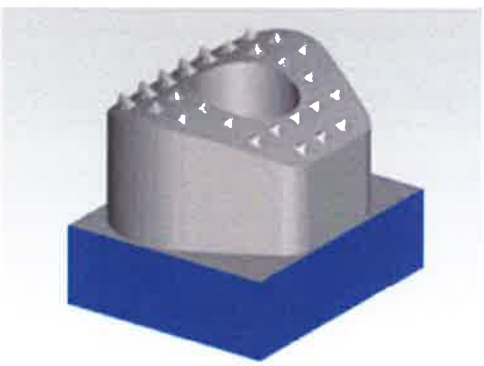
Step 1: Profile milling



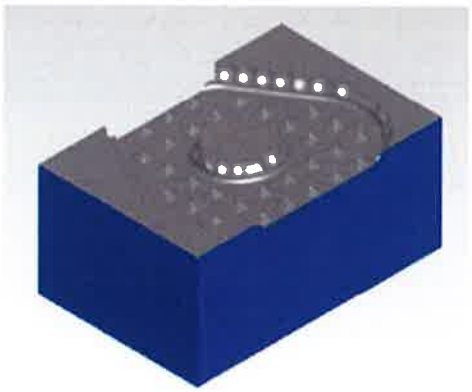
Step 2: Hole drilling



Step 3: Rough surface milling

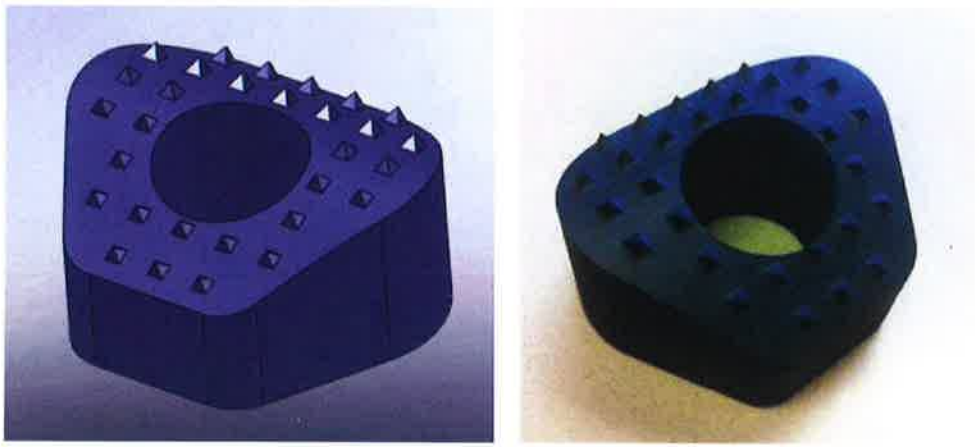


Step 4: Finish surface milling



Step 5: Cage bottom fabrication simulation

Figure 5.12 Steps in automated milling process (Rutgers Manufacturing Automation Laboratory).



(a) (b)

Figure 5.13 (a) Designed and (b) prototype spinal spacer cage fabricated with milling process (Rutgers Manufacturing Automation Laboratory).

reversing the part, profile milling and hole were machined deeper than the specified cage dimension. After flipping the stock to fabricate the bottom surface, the effect resulting from misalignment would be minimized. Even though the starting point is inaccurate, there would be minimal chips left along the boundary, which could be easily cleaned up. The bottom surface had to be 15.5 mm depth surface milled, then fabricate using the same tools, methods, and sequence with the superior. Fabricated prototype using this methodology is shown in Figure 5.13.

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