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POTENTIAL BIOMEDICAL APPLICATIONS OF ION BEAM TECHNOLOGY

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POTENTIAL BIOMEDICAL APPLICATIONS OF ION BEAM TECHNOLOGY

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Abstract

Electron bombardment ion thrusters used as ion sources have demonstrated a unique capability to vary the surface morphology of surgical implant materials. The microscopically rough surface texture produced by ion beam sputtering of these materials may result in improvements in the biological response and/or performance of implanted devices. Control of surface roughness may result in improved attachment of the implant to soft tissue, hard tissue, bone cement, or components deposited from blood. Potential biomedical applications of ion beam texturing discussed include: vascular prostheses, artificial heart pump diaphragms, pacemaker fixation, percutaneous connectors, orthopedic prosthesis fixtion, and dental implants.

Introduction

Electron bombardment ion thrusters used as ion sources have demonstrated a unique capability to vary the surface morphology of materials in a controlled manner.(1) The energetic ion bombardment of materials may result in a biomedical application of ion beam technology. Ion beam sputtering of various polymers and metals used as biological implant materials(2) can produce a controlled microscopic roughening of the surfaces of these materials. This controlled roughening has the potential to improve the performance of prosthetic materials (synthetic materials used to replace natural tissue or organs).

References 1 and 2 present details of the ion source and the results sputter texturing various materials. This paper will emphasize the potential medical applications of implantable devices whose surfaces have been textured by ion beam sputtering.

In the general study of prosthetic materials one is interested in the changes in the healing process that result from the presence of an implant. In order to develop clinically acceptable materials, the influence of material parameters on the biological response must be understood. The concept of biocompatibility of a material cannot be discussed without consideration of the intended function of the implant and its site of implantation. The details of the healing response elicited by an implanted material are dependent upon the biological environment. Different processes must be considered depending whether use is in hard or soft tissue or in contact with blood. The materials used to fabricate implants must interact with the healing process particular to the implantation site in such a way that the functional capability of the implant is maintained. In addition, the implant must not indirectly lead to complications that become harmful to the host.

Soft Tissue Implants

This section discusses ion beam sputtering of implants exposed to soft tissue or blood. In addition, a general discussion of ion roughening (applying to all sections) will be presented.

Vascular Prostheses

To date, there is no known successful synthetic substitute for small (<5 mm dia) arteries. This is a result of the biological response at the blood-prosthesis interface. The general healing process associated with vascular (blood contacting) prosthesis (e.g. artificial veins or arteries) involves the deposition of various components from the blood onto the material. Plasma proteins adsorb instantaneously onto surfaces exposed to blood.(3) This is followed by platelet and leukocyte (white blood cell) adherence and the polymerization of fibrin from the blood. These components build up to form a layer called a thrombus which covers the material. The thickness and composition of the thrombus, and its development with time, have been shown to be dependent upon the material characteristics.(4) The most favorable end-point of the healing process is the generation of a viable layer of endothelial cells covering the implanted material. Endothelial cells normally line the entire vascular system and are considered the ideal thrombosis resistant surface.

The deposit of thrombus on a vascular prosthesis can lead to two major complications: occlusion (blockage) or embolization (detachment of all or a portion of the thrombus). If the thickness of the thrombus continues to increase without passivating, then the thrombus will eventually occlude the prosthesis and the implant will no longer be functional. Emboli are potentially dangerous because they are carried downstream by the flow and can become trapped in the small vessels of vital organs and cause necrosis (death) in the tissue normally supplied by these vessels.(5) Firm attachment of the thrombus to the implant is desired to avoid embolization. The surface texture is a characteristic of the material that has been shown to affect the adherence of the thrombus layer.(6)

The manner in which controlled variations in the surface texture of prosthetic materials affects thrombus attachment has not been critically evaluated. The majority of previous research on this topic has either (1) used different material coatings, such as flocking, to vary surface texture or (2) been limited in the ability to introduce controlled changes in surface texture while investigating a single material. The use of different materials to study surface texture does not allow one to separate the contributions to the healing response that result from changes in the materials versus changes in the surface texture. This problem can

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potentially be overcome by the use of ion beam technology. Ion beam sputtering techniques enable one to study a single material that has controlled variations in surface texture.

An ion thruster used as an ion sputter source can easily produce low energy neutralized ion beams suitable for sputtering textures in polymers without causing thermal damage. Operation of the ion thrusters with inert gas as a sputter ion source prevents contamination of the implant surface. An 8-cm xenon-ion source has been used to texture segmented polyurethane vascular implants.[7] The ion source had dished grids and used hollow cathodes for the main cathode and neutralizer. A schematic diagram of the 8-cm-xenon source is shown in figure 1. The implants were sputter etched with a 500 eV, 10 mA Xe ion beam for 30 minutes at a location 20 cm downstream of the ion extraction system. This resulted in a current density of 20 μA/cm^2 at the implant surface.

The implants were 3 mm wide x 5 mm long x 0.25 mm thick.[2] Two sutures, attached to the back of the implant had to be protected from back sputtered facility material. A special sample holder shown in figure 3 was constructed to hold the implants and to provide the necessary protection of the sutures.

After sputtering, the implants were immediately covered and handled thereafter, in dust-free conditions. The implants were removed from the sample holder in a clean room and placed (suspended by the sutures) in glass bottles for transportation to the animal surgery facility. The implants were then put into small teflon tubes (to avoid contamination during surgery) and sterilized with ethylene oxide.

A series of experiments were performed to investigate the effect of a sputtered implant surface on the deposition of the layer of thrombus. The materials were implanted in two forms: sputtered and unsputtered. Figure 4 shows the surface morphology of sputtered and unsputtered segmented polyurethane. The sputtered material has a microscopically scaly surface texture, whereas, the unsputtered material is relatively smooth.

The implantation procedure used for the tests involves implanting a longitudinal section of a tube into canine femoral and carotid arteries.[8] The implant is secured against the inside wall of the artery using sutures, thereby exposing the implant to the blood and adjacent vessel endothelium. Implants were removed at 1 hour, 1 day, and 4 days. Specimens were fixed in osmotically balanced glutaraldehyde buffered with cacodylic acid, dried at the critical point, and examined by scanning electron microscopy.

The sputtered and unsputtered implants elicited extremely different blood responses after only 1 hour of implantation. This difference is shown by figures 5 and 6, in which both micrographs were taken at an original magnification of 200x. The unsputtered implant (fig. 5) is covered with a monolayer of platelets and leukocytes after 1 hour of implantation. Figure 5 shows a boundary between a predominantly platelet area at the top and a leukocyte area at the bottom. In distinct contrast is the surface of the sputtered implant after 1 hour of implantation (figs. 7,8,9). The accumulation of blood components on the material surface is greatly increased for the sputtered surface implant. The aggregation of this deposition into numerous pillars is extraordinary. These pillars are composed of platelets and leukocytes (fig. 7). The surface of the material between the pillars is covered with a layer of fibrin, which is interspersed with platelets and leukocytes (fig. 8). In an area that is not covered with fibrin, cells can be seen directly adherent to the sputter-etched material. A leukocyte is shown attached to the sputtered material in figure 9, which also shows the scaly surface texture that results from the sputtering process.

After 1 day of implantation the layer of thrombus on both the sputtered and unsputtered materials had reached a thickness of 50 to 100 microns. The surface of the thrombus is composed primarily of platelets and leukocytes (fig. 10(a)). The layer of thrombus has a variable topology, and in depressions strands of fibrin are often observed. Erythrocytes (red blood cells), leukocytes, and platelets are trapped in such deposits of fibrin. Single leukocytes are occassionally observed flattened out on the surface of the thrombus after 1 day of implantation. These flattened leukocytes are more numerous on the thrombus covering the sputter-etched material (fig. 10(b)).

After 4 days of implantation the surface of the thrombus covering both the sputtered and unsputtered implants appears very similar when viewed by scanning electron microscopy. Flatted out leukocytes on the surface of the thrombus are often in aggregates, forming islands of flat cells (fig. 11). These flattened leukocytes are morphologically similar to endothelial cells and are thought to have the ability to transform into true endothelial cells. The underlying thrombus still has a variable surface morphology and is composed of platelets, leukocytes, and fibrin with entrapped erythrocytes.

These results imply the possibility that the sputtering process may be used to affect thrombus attachment to a material implanted in the vascular system. The 1-hour response shows a clear increase in the amount of deposition from the blood onto the sputter-etched material. This may represent an improved adherence of the thrombus to the implant and the potential to decrease the occurrence of embolus formation.

In addition to the natural sputter-etched surface roughness, a larger scale of roughness can be obtained by covering the segmented polyurethane with a fine electroformed nickel mesh during sputter etching. Figure 12 shows the surface morphology of segmented polyurethane after sputtering while covered with a $5x10^{-4}$ cm thick nickel mesh. The use of such screens in the sputtering process enables one to test controlled surface variations while investigating a single basic material. Screens can be used that have a range of grid sizes and thicknesses to make implants with varying pore size, depth, and spacing. The effect of these parameters on the healing process can be evaluated in order to determine the combination that best serves the intended function.

<u>Artificial Heart Pump Diaphragm</u>

Artificial heart pump components must have surfaces appropriate for soft tissue and blood compatibility. In addition the active pumping elements must have high flex life capabilities (nearly half a billion cycles in 10 years). An artificial heart assist pump diaphragm is shown in figure 13. The diaphragm must either remain free of thrombus or maintain a strong adherence of the thrombus to the diaphragm surface.

The need for a firm thrombus attachment to avoid embolization has led to the development of many methods to provide a rough surface on the blood side of the diaphragm. Velour fabric bonded to the diaphragm increases the surface roughness and improved the thrombus attachment but has been shown to have inadequate flex life.[9] Porous diaphragm surfaces have also been fabricated by coating the diaphragm with a layer of polymer containing a dispersion of common salt crystals.[9] After curing the salt is dissolved leaving a porous structure with 0 - 150 μm pores. Both these and other similar techniques are not ideal for experimentation in that the ability to introduce controlled changes in the surface texture is limited.

Ion beam sputter-etching is being examined as a candidate technique for the investigation of controlled changes in the surface morphology of artificial heart pump diaphragms. A 32-percent carbon impregnated polyolefin was ion beam sputtered using a 5-cm diameter mercury ion source. The ion source had a hollow cathode, dished grids, and a double-stranded tantalum wire loop neutralizer. The neutralizer loop was coated with an electron emissive mix and had a diameter 6 mm larger than the ion beam diameter. It was positioned 1 cm downstream of the accelerator grid plane. The source was operated at 25 mA ion beam current at 700 electron volts ion beam energy with the samples located 20 cm downstream of the accelerator grid. Figure 14 is a scanning electron micrograph of sputtered and unsputtered carbon impregnated polyolefin.

Sputter-etching the polyolefin with an overlay of electroformed mesh results in a formation of pockets in the surface similar to the effect shown in figure 12 for segmented polyurethane. A cross-section of the material (fig. 15) after sputtering with an overlay of 5×10^{-4} cm thick nickel mesh. The depth of the sputter erosion in each pocket is dependent upon the sputter erosion life (and thus the thickness) of the mesh used and the width of the pocket is controlled by the choice of the mesh openings. Therefore, the surface texture can potentially be optimized to provide firm attachment of the thrombus. The ability to control the depth of the pockets is also important because of the metabolic requirements of the thrombus. Tissue in deep pores cannot be adequately supplied by diffusion of nutrients and will die without growth of capillaries into the thrombus. The thrombus in shallow pores on the other hand can be nourished by diffusion and tissue necrosis in the pores can be prevented. Calcification at sites of necrosis would stiffen the diaphragm and should therefore be avoided. Another potential advantage of ion beam sputtered carbon impregnated polyolefin is that the carbon concentration on the surface has been measured to be enhanced due to the relatively low sputtering yield of carbon. Carbon has demonstrated good biocompatibility, therefore, a high surface abundance of carbon may improve the blood compatibility of the surface.

Pacemaker Fixation

Biological implants whose bulk density exceeds that of the surrounding soft tissue have forces tending to displace them upon sudden movement. This can result in reorientation or displacement of devices such as implanted power packs for pacemakers (fig. 16). By providing an ion beam textured surface to the power pack its mechanical attachment to the soft tissue may potentially be improved.

Surface roughness was produced by ion beam texturing an alloy commonly used for packaging pacemaker power packs. The composition of the cobalt-chromium alloy[10] used is given in table I. A scanning electron micrograph of the cobalt-chromium alloy after ion beam texturing is shown in figure 17. This sample was sputtered for 5 hours by the 8-cm xenon-ion source operating at 20 cm sample-to-source distance and 100 mA, 1000 eV ion beam. Ingrowth of connective tissue onto roughened surfaces is thought to improve mechanical adherence of the tissue to the prosthesis and further testing is needed to evaluate the biocompatibility as well as the effectiveness of this treatment in improving the adherence. Again, however, the advantage of the ion beam texturing is the ability to control variation in the surface morphology to produce the best surface for this function.

Percutaneous Connectors

Percutaneous connectors are connectors that pass through the skin. They are used as an electrical, liquid, gaseous or mechanical conveyance. Examples of perctaneous connectors are the leads for the intra-aortic balloon pump[11] and the electrical stimulation of muscle.[12] Percutaneous connectors require an effective fluid seal at the skin-connector interface, and it is essential that this seal be resistant to infection. The surface morphology as opposed to bulk porosity of percutaneous connectors is known to play a role in the development of an effective seal.[13] The ion beam texturing of percutaneous connectors may potentially allow a well-nourished ingrowth of connective tissue thereby contributing to the requirements for an effective fluid seal.

Hard Tissue Implants

This section discusses potential biomedical applications of ion beam technology in the area of implant devices placed within or attached to calcified (bone) tissue.

Orthopedic Prosthesis Fixation

Orthopedic prosthesis (artificial bone or joints) require firm mechanical attachment of the prosthesis to the bone. A femoral head prosthesis, for replacement of the head and neck of the femur (thigh bone) is shown in figure 19 in comparison to the upper portion of the femur. The stem of the hip prosthesis is driven into the medullary canal (the central cavity) of the femur and room-temperature-curing polymethyl methacrylate is used to cement the stem of the prosthesis to the bone. Because the bond is typically weak between the cement and prosthesis, loosening may occur. This loosening causes unloading of stresses on the bone and stem in some areas and overstressing the bone and prosthesis in other areas. Unloading of stresses in the femur can lead to resorption (deterioration) of the bone tissue. Overstressing the prosthesis stem can result in fracture of its stem. Ion beam texturing of the prosthesis stem (fig. 18) may potentially eliminate the need for polymethyl methacrylate cement in the younger patient. In older patients where cement is used, the textured prosthesis surface may improve the bond between the cement and the stem.

Materials for orthopedic prosthesis that have been successfully textured are: surgical stainless steel[14] cobalt-chromium alloy (table I), and titanium 6%Al-4%V. The texturing was accomplished by sputter etching the alloy while simultaneously depositing sputtered tantalum on the surface of the alloy[1,2] The geometry of the texturing technique is shown in figure 19. The function of the tantalum (called the seed material) is to provide, through surface mobility, sputter resistant sites separated by higher sputtering yield nontantalum areas. This is thought to foster the development of a sputtered ridge or cone and valley texture on the alloy.[1] Scanning electron micrographs of surgical stainless steel, cobalt-chromium alloy, and titanium 6%Al-4%V after ion beam texturing are given in figures 20, 17, and 21, respectively. Preliminary tests indicate a substantial improvement in the polymethyl methacrylate bond strength to ion beam textured titanium 6%Al-4%V compared to a smooth surface. Further testing required include additional bond strength tests, biocompatibility tests, and tensile tests on surface textured samples.

Dental Implants

Dental implants (tooth substitutes) provide restoration of masticatory (chewing) function, appearance, and speech. The requirements for a successful dental implant are unique in that a satisfactory biological response to the implant must occur at a bone-implant interface and the gingival (gum) tissue - implant interface. Figure 22 is a photograph of an endosteal blade vent implant. This type of dental implant is implanted into the bone that had previously supported natural teeth.[15] After sufficient ingrowth of the bond has occurred the upper portion of the implant is then capped with a crown providing the appearance and function of a natural crown (portion of tooth above gum line). Figure 23 depicts an x-ray dental restoration using endosteal blade vent implants. The functional performance and disease resistance of the implant is a measure of how successfully the implant simulates the natural tooth. Figures 24(a) and (b) are scanning electron micrographs of natural tooth cementum (root) and the simulated root of the endosteal blade vent implant, respectively. As can be seen, the natural tooth cementum is much rougher than the unsputtered implant surface. Figure 24(c) is a scanning electron micrograph of an ion beam textured endosteal blade vent implant. The titanium implant was sputter etched for 30 minutes by a 100 mA 1800 electron volt xenon ion beam in the presence of a tantalum seed. The seed material was then removed and the sample was etched for one minute at the same beam conditions. The implant was located 10 cm downstream of the 8-cm ion source. The microscopically rough ion beam textured surface may more satisfactorily simulate the natural tooth cementum surface morphology. Evaluation of the ion beam textured endosteal blade vent implants in dogs is currently being performed under NASA Grant NSG-3110 at Mount Sinai Hospital, Cleveland, Ohio. If the implant surface more nearly simulates the natural surfaces, then improvements in mechanical fixation and orientation of the periodontal ligaments (the connective tissue that surrounds a natural tooth) may result.

Concluding Remarks

Ion beam texturing can be used to produce controlled variations in the surface texture of biological implant materials. Many prostheses require materials that will elicit a firm attachment of the surrounding tissue to the implant material. The mechanical strength of the tissue attachment and the viability of the tissue at the tissue-implant interface depend on the implant surface morphology. Ion beam texturing is potentially useful in the study of the effect of surface morphology on the biological response because of the ability of this technique to control the surface roughness. Controlled studies of surface morphology will enable the determination of the surface texture that interacts with associated healing process in order to most effectively meet the desired function of the implant.

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Mr. Thomas Gurley - Goodyear Tire and Rubber Co., Akron, Ohio

Dr. Joseph Schulman - Pacesetter Systems, Inc., Sylmar, California

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Table I - Composition of Cobalt-Chromium Alloy for Surgical Implants

Element	Composition, percent	
	min	max
Chromium	19.0	21.0
Tungsten	14.0	16.0
Nickel	9.0	11.0
Iron	----	3.0
Carbon	0.05	0.15
Silicon	----	1.00
Manganese	----	2.00
Cobalt	----	remainder

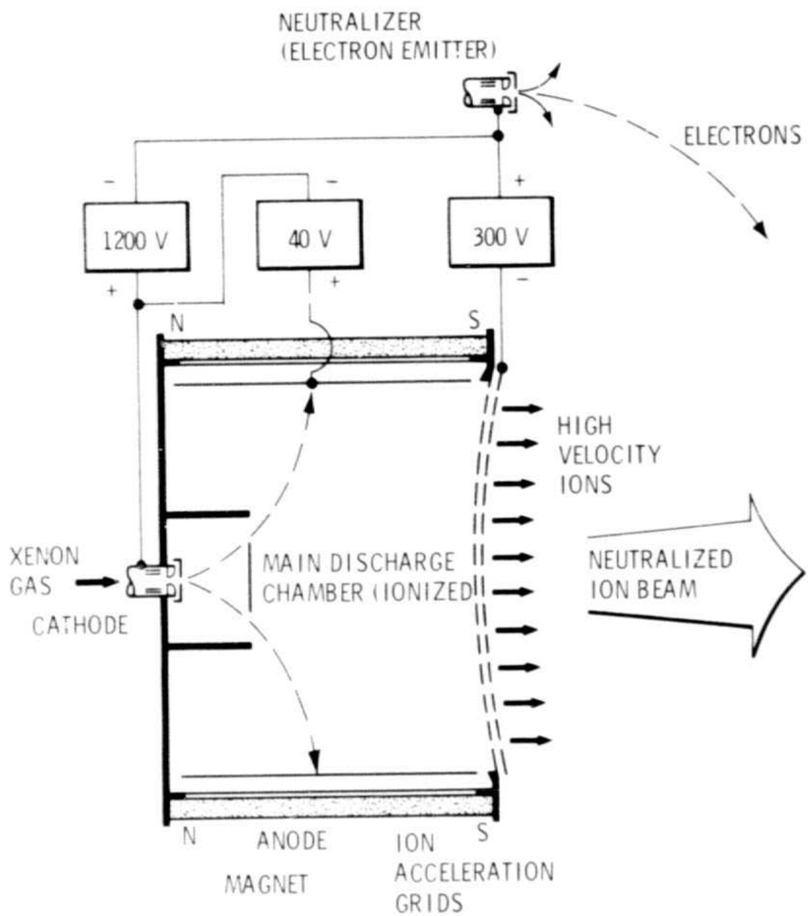


Figure 1. - Schematic drawing of 8 cm xenon ion source.

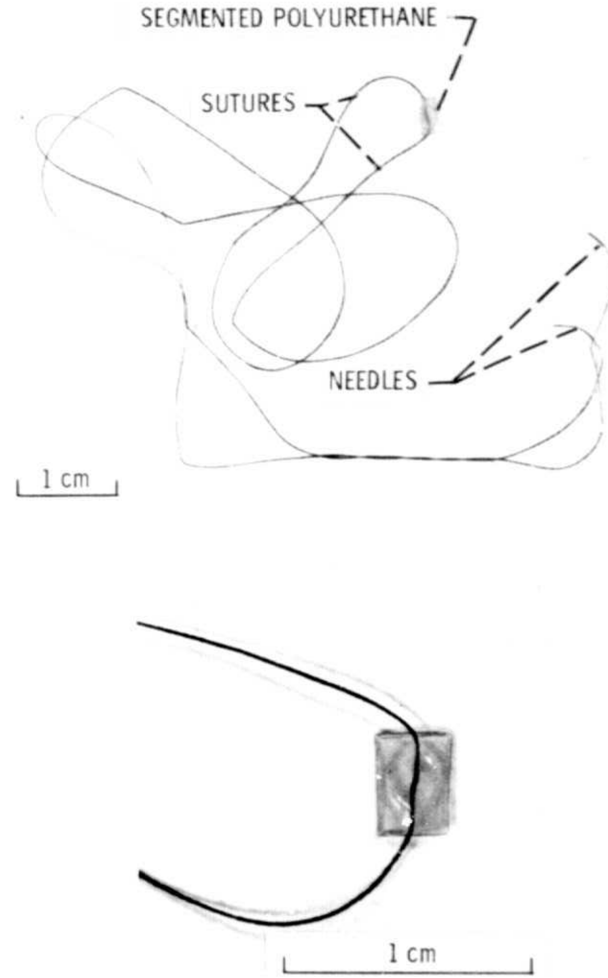


Figure 2. - Vascular implants.

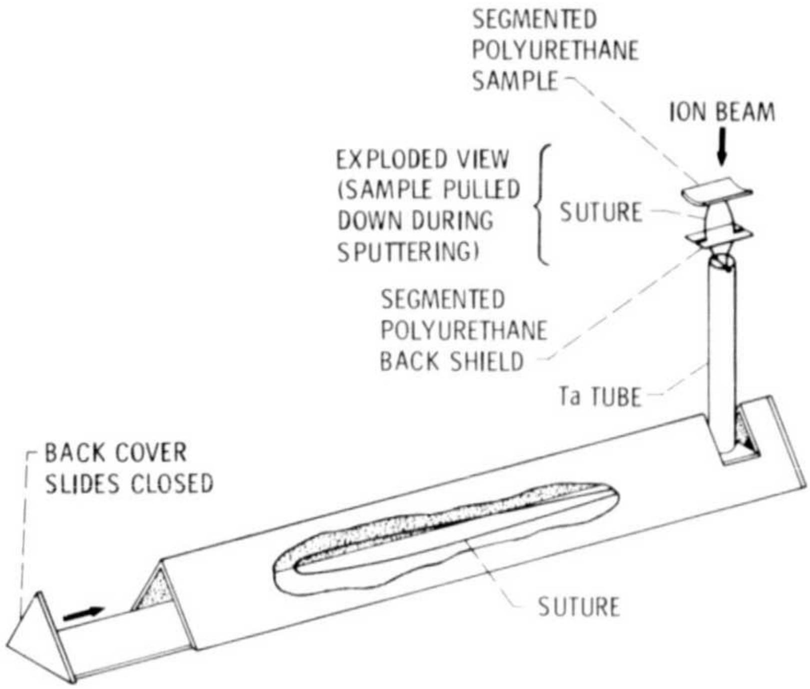
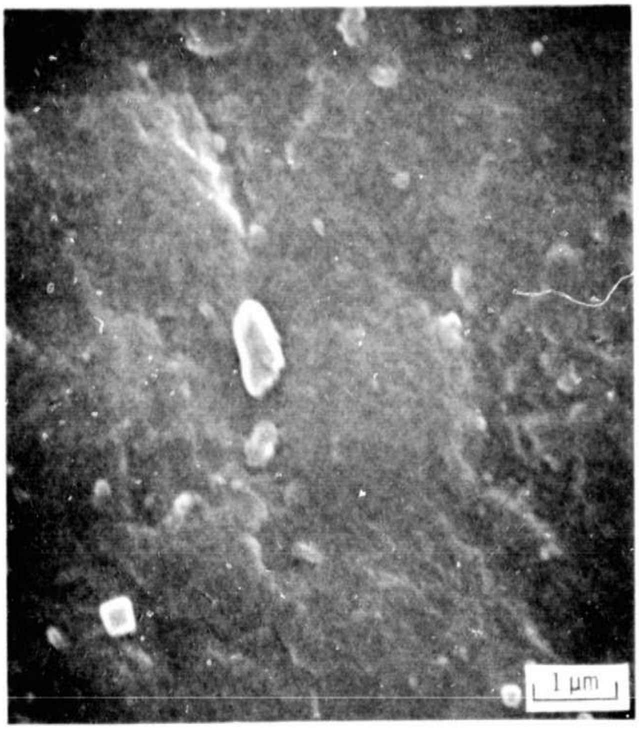
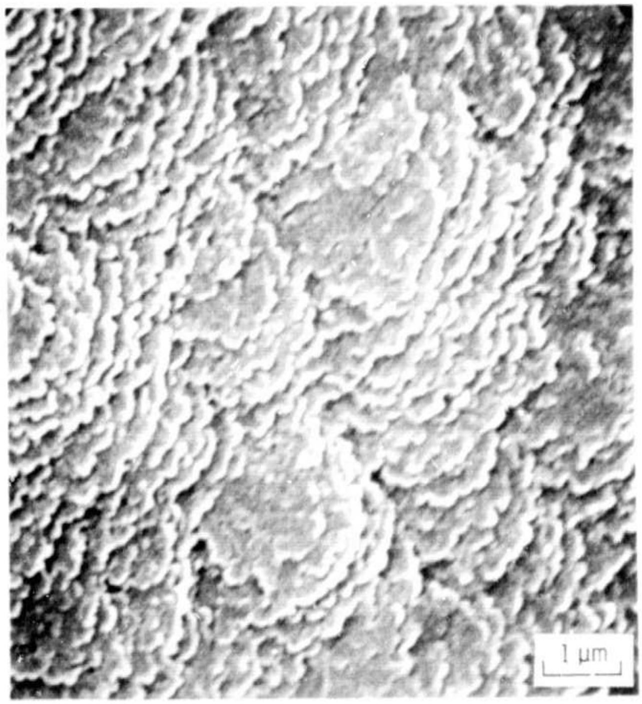


Figure 3. - Sample holder for sputter etching vascular implants.



(a) BEFORE ION BEAM SPUTTER ETCHING.



(b) AFTER ION BEAM SPUTTER ETCHING.

Figure 4. - Scanning electron micrographs of segmented polyurethane.

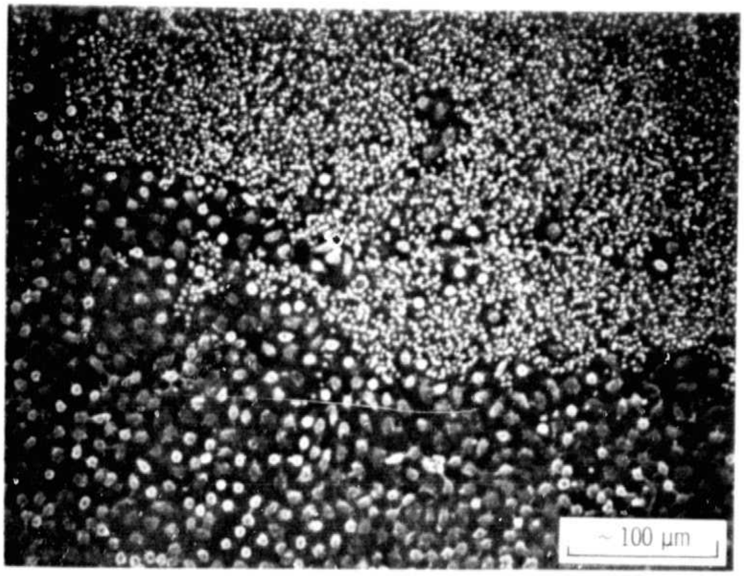


Figure 5. - Unsputtered implant after 1 hour of implantation.

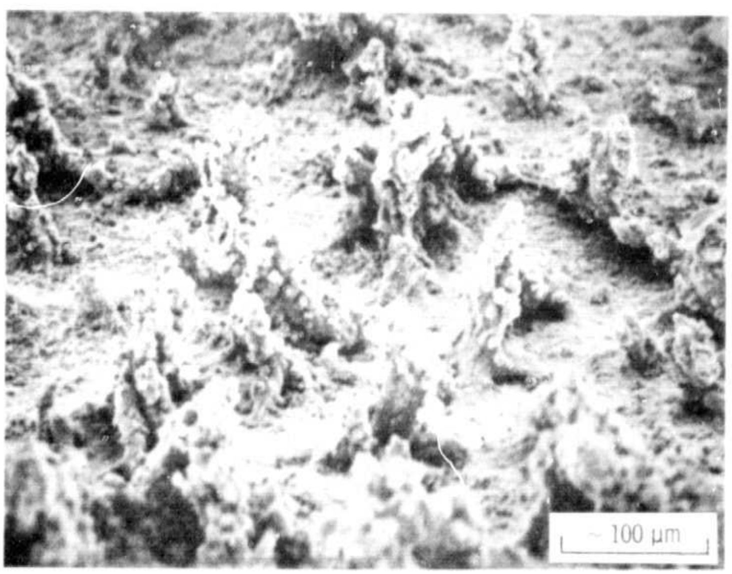


Figure 6. - Sputter etched implant after 1 hour of implantation.

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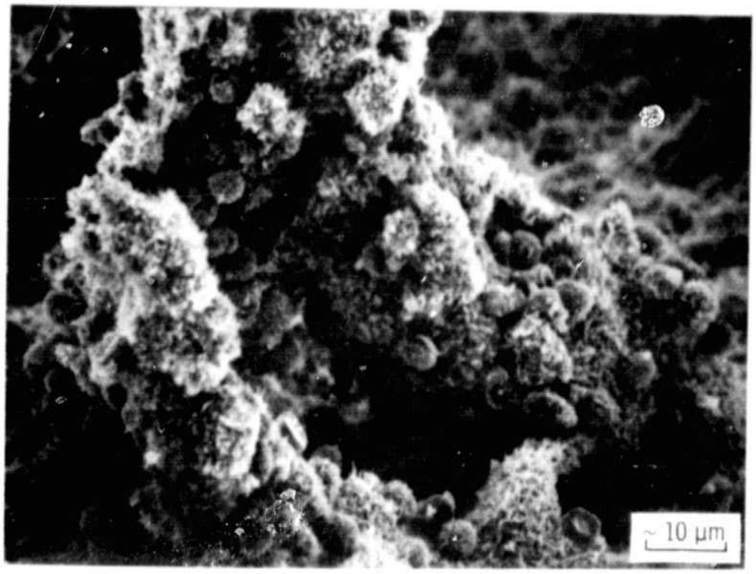


Figure 7. - Pillars of platelets and leukocyctes on sputter etched implant of Figure 6.

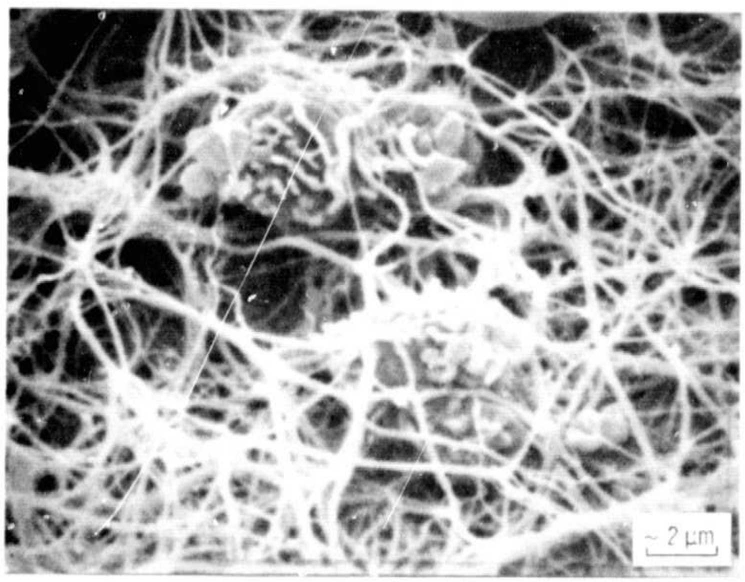


Figure 8. - Fibrin between pillars on sputter etched implant.

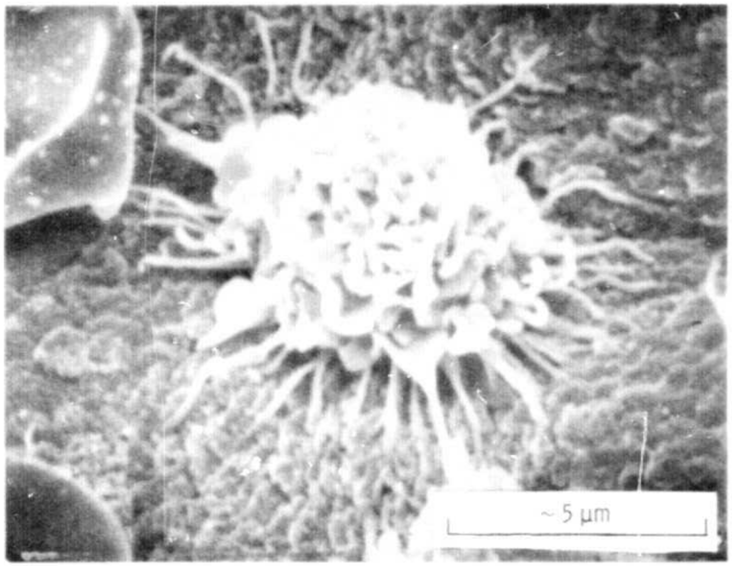
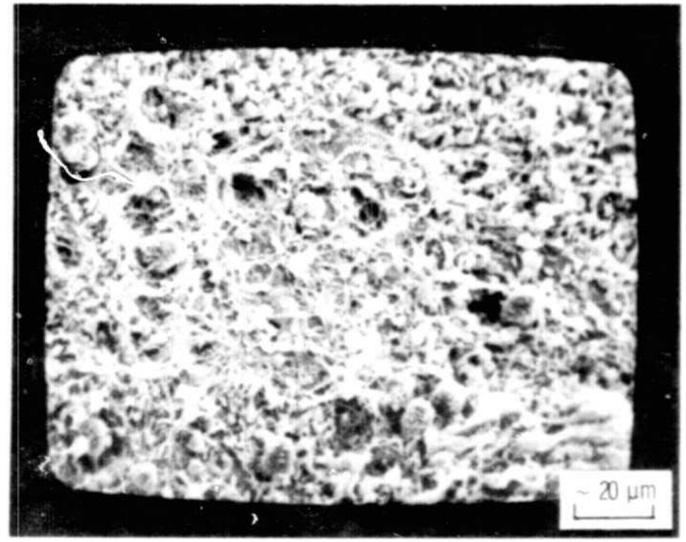
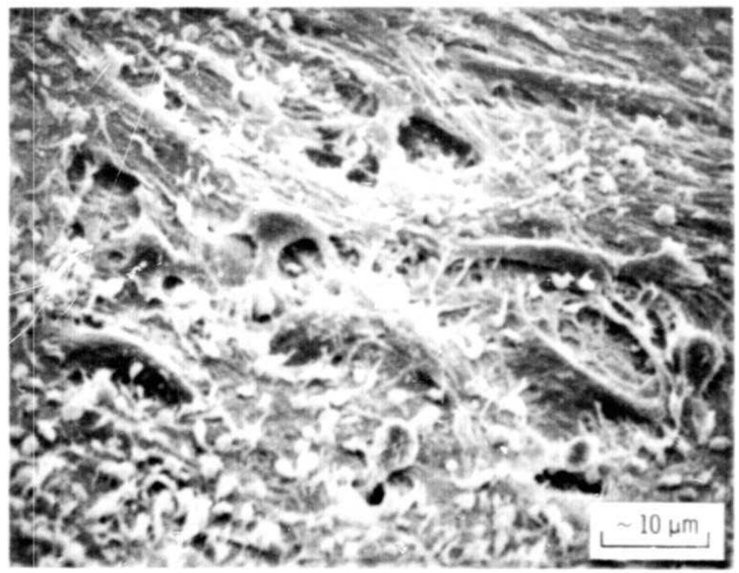


Figure 9. - Leukocyte on sputter etched implant surface.

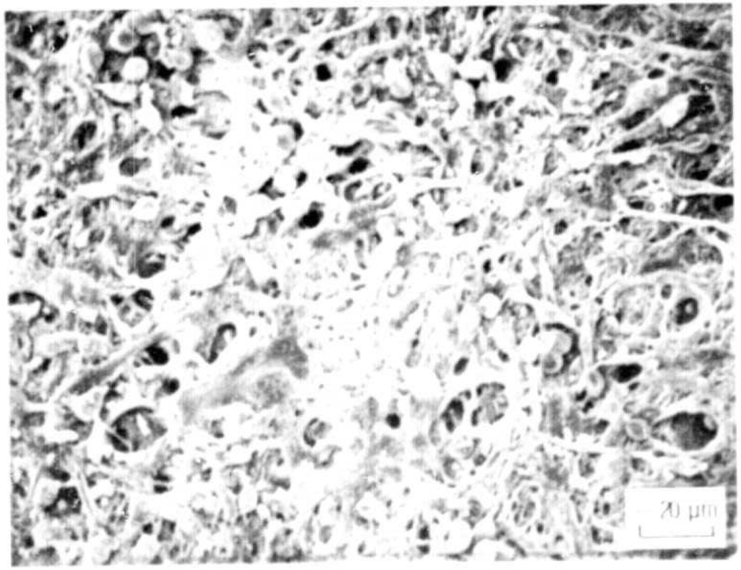


(a) GENERAL APPEARANCE OF SURFACE OF THROMBUS.

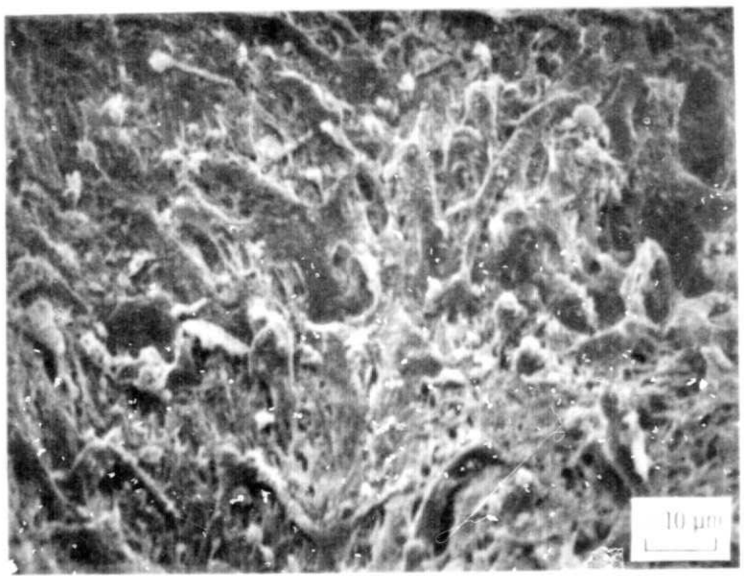


(b) MORE FREQUENT APPEARANCE OF FLATTENED LEUKOCYTES ON THROMBUS COVERING SPUTTER ETCHED IMPLANT SURFACE.

Figure 10. - Thrombus surface after 1 day of implantation.



(a) UNSPUTTERED.



(b) SPUTTER ETCHED.

Figure 11. - Comparison of surface of thrombus covering implants after 4 days of implantation.

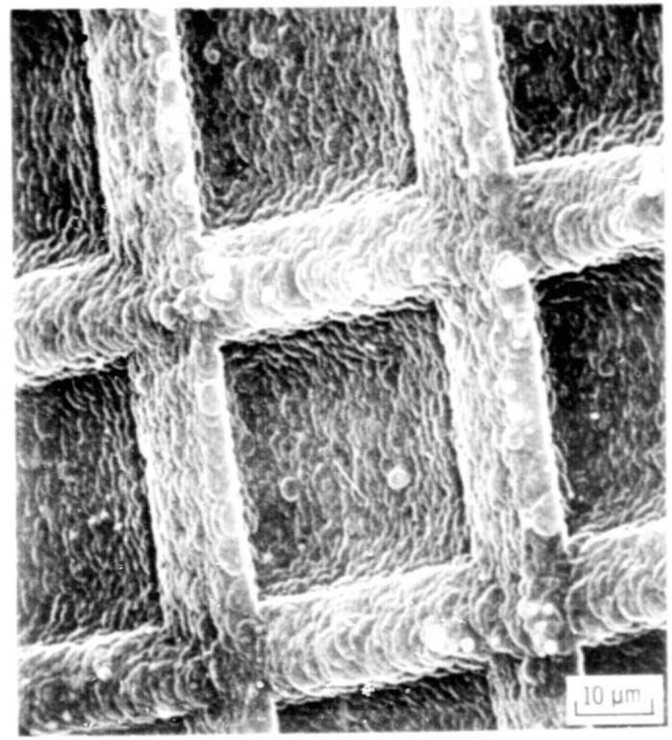


Figure 12. - Scanning electron micrograph of segmented polyurethane after sputter etching while covered with a nickel photoformed mesh. Pockets are ~ 8 µm deep.

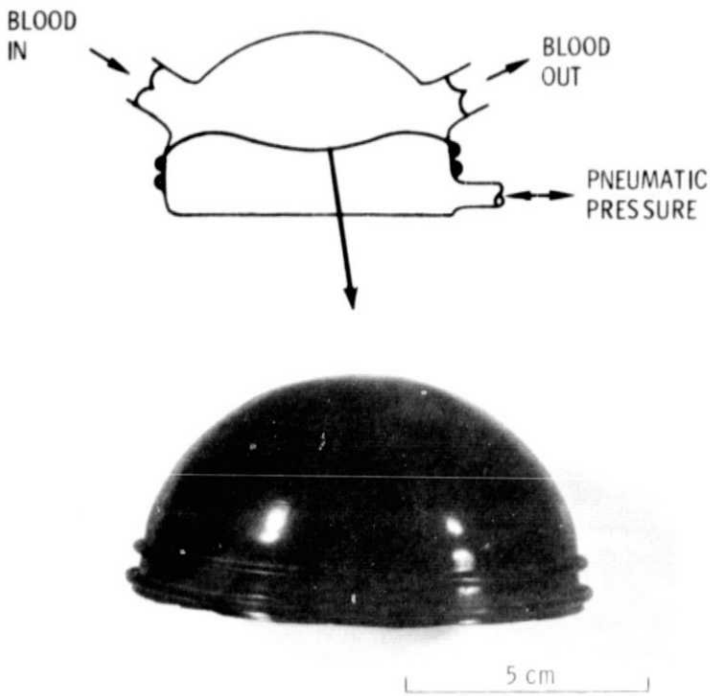
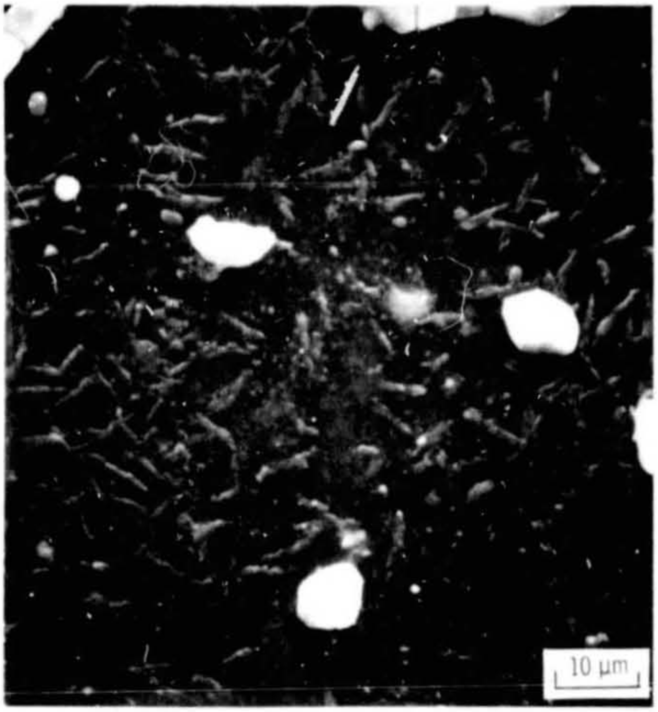
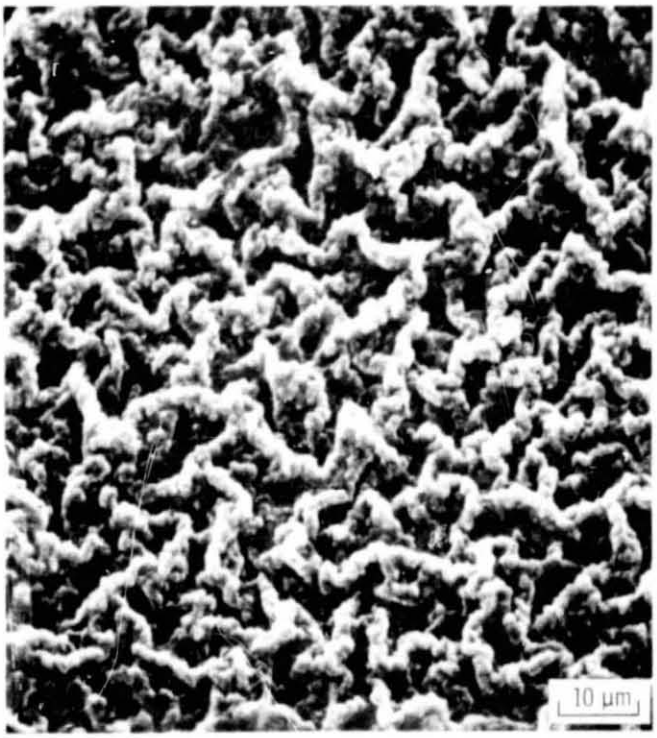


Figure 13. - Artificial heart assist pump.



(a) BEFORE SPUTTER ETCHING.



(b) AFTER SPUTTER ETCHING.

Figure 14. - Scanning electron micrographs of carbon impregnated polyolefin.

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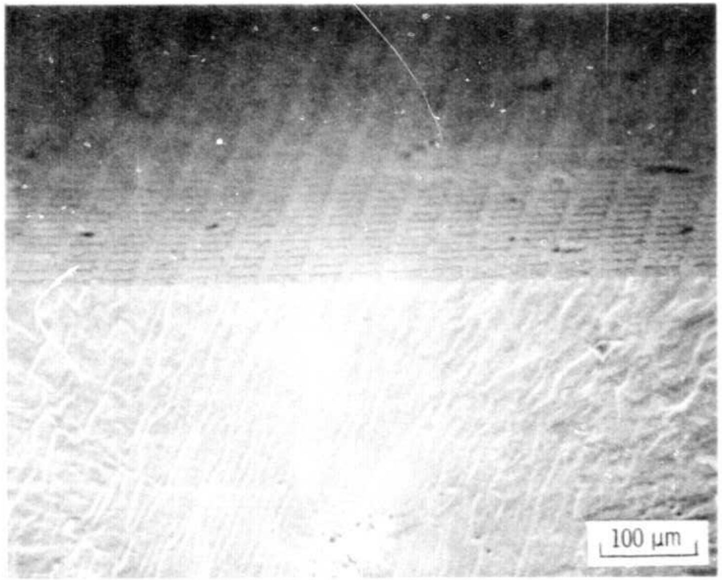


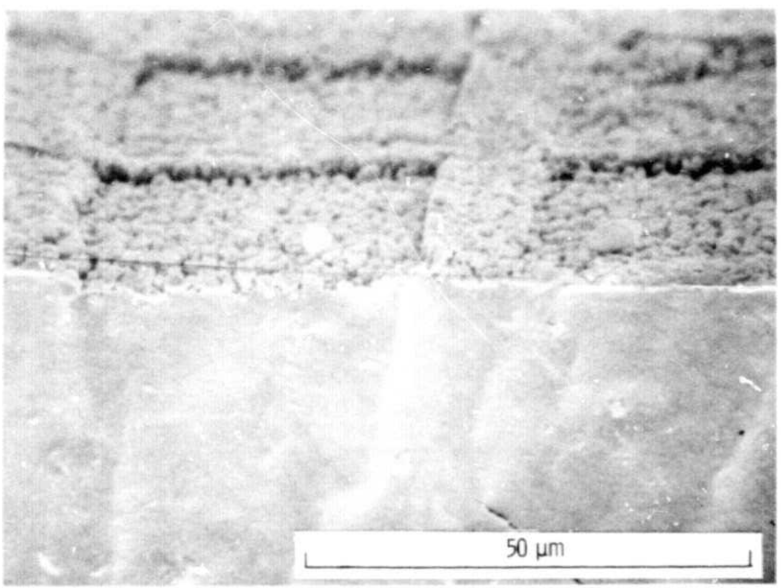


Figure 15. - Freeze fracture sample of sputter-etched carbon impregnated polyolefin that has been covered by electroformed mesh during sputter etching.

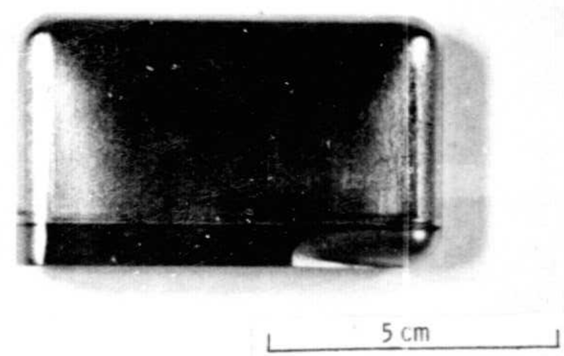


Figure 16. - Pacemaker power pack.

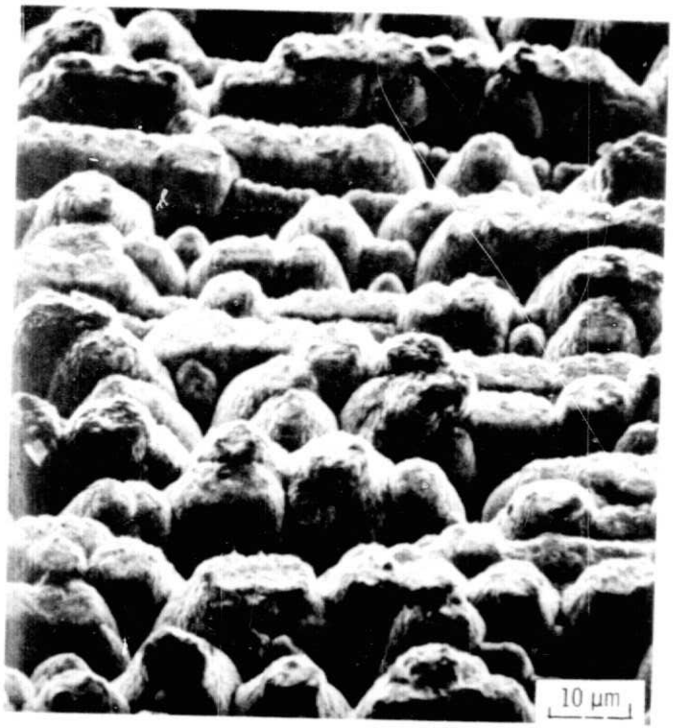


Figure 17. - Ion beam textured cobalt-chromium alloy of Table I.

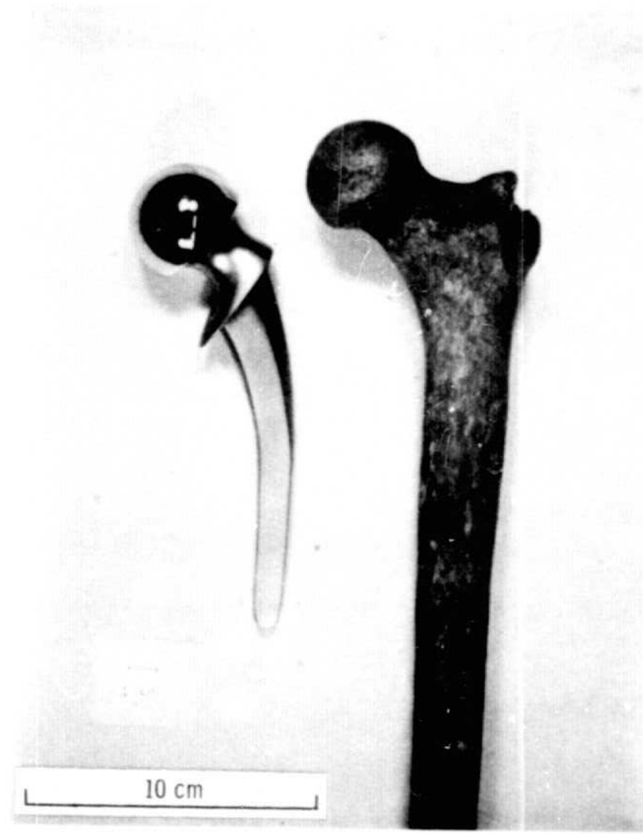


Figure 18. - Hip prosthesis and upper femur.

Figure 19. - Texturing technique geometry.

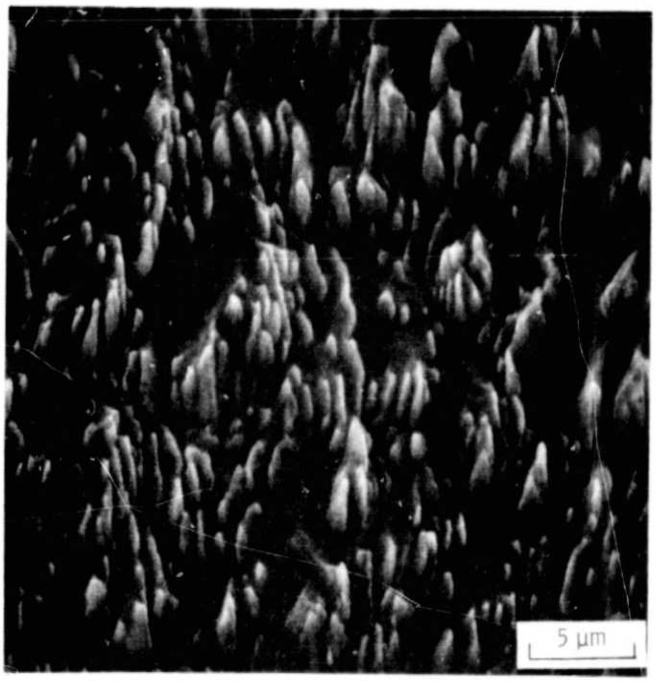
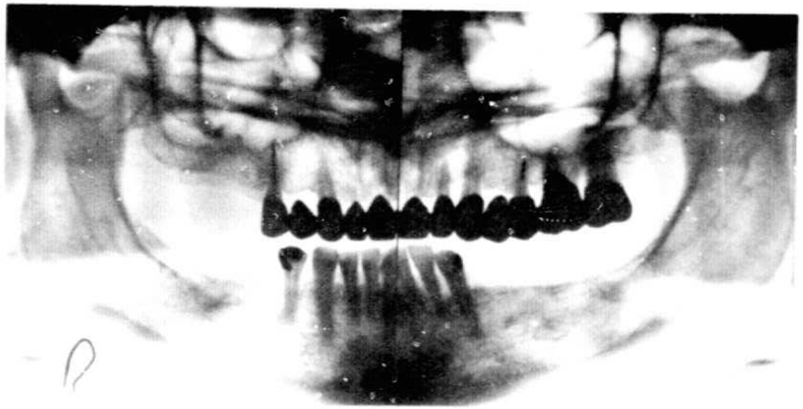


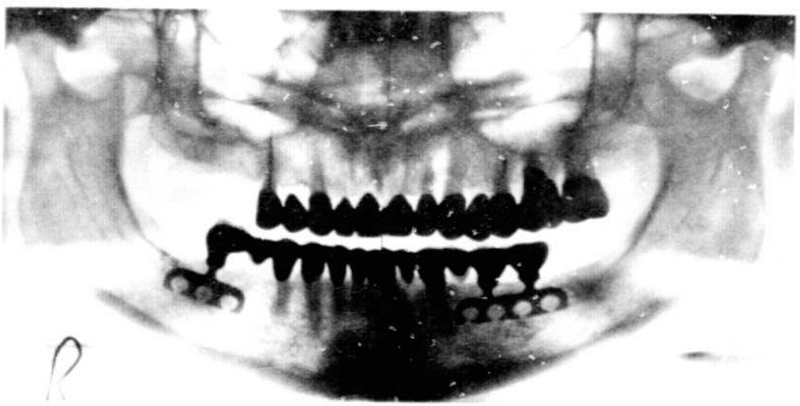
Figure 20. - Ion beam textured surgical stainless steel (ASTM designation F 55-71).

Figure 21. - Ion beam textured titanium, 6 percent Al and 4 percent V.

Figure 22. - Titanium endosteal blade vent implant.

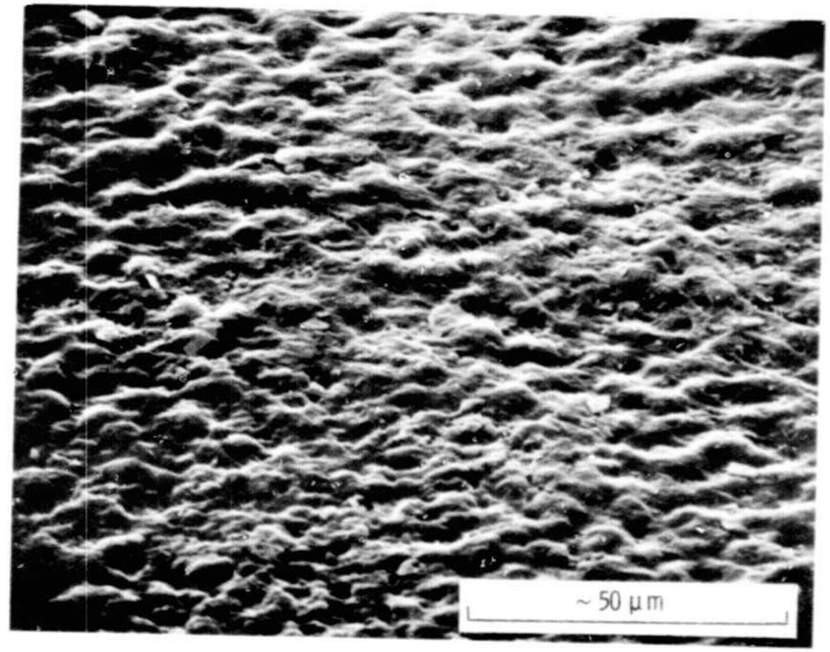


(a) NATURAL TEETH MISSING.



(b) CROWN ATTACHED TO IMPLANTS.

Figure 23. - X-rays of dental restoration with endosteal blade vent implants.



(a) NATURAL TOOTH C :MENTUM.

Figure 24. - Scanning electron :.icrographs of surfaces exposed to the calcified tissues of the oral cavity.

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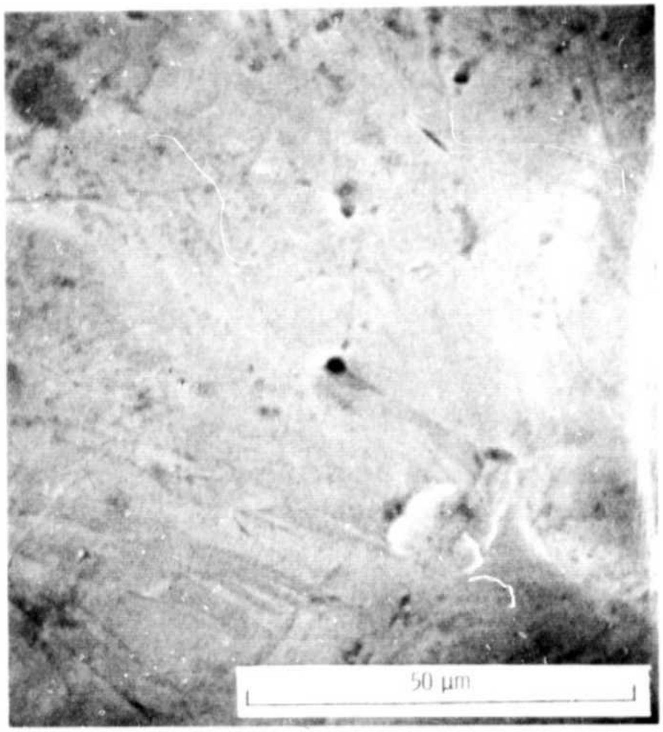
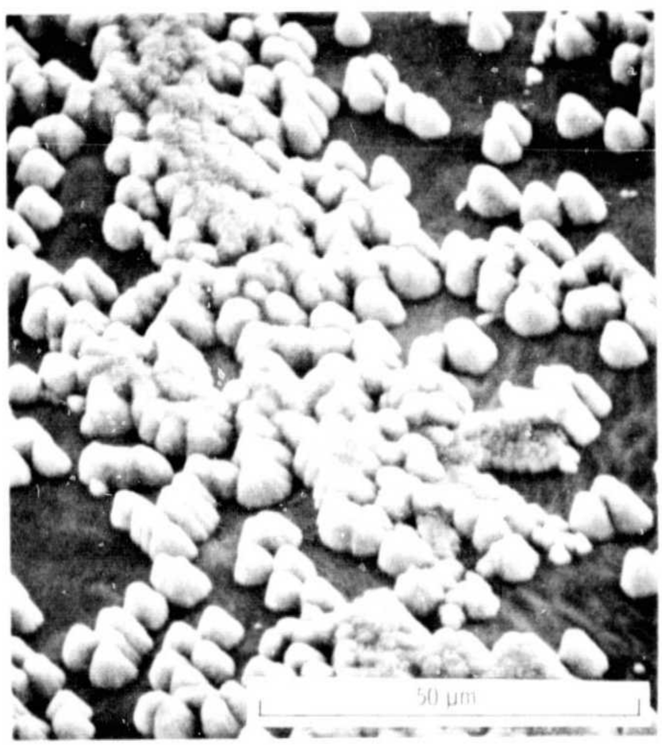


(b) TITANIUM ENDOSTEAL BLADE VENT IMPLANT SURFACE.



(c) ION BEAM TEXTURED TITANIUM IMPLANT.

Figure 24. - Concluded.