SHEng
SMART HEALTHCARE ENGINEERING
2023-1-RO01-KA220-HED-000159985

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STAINLESS STEEL IN HEALTHCARE FACILITIES

Part 3

Class content material

This document is part of a training materials collection developed within the Erasmus+ project “Smart healthcare engineering”, SHEng, project No. 2023-1-RO01-KA220-HED-000159985.

The collection is intended for engineering students and professionals working in the healthcare sector. It covers technical subjects relevant to hospital infrastructure, equipment, materials and support services, helping readers understand how engineering contributes to safe patient care and the reliable operation of healthcare facilities.

These materials support classroom teaching and independent study. They should be used alongside the project handbook and the presentations, courses and other learning resources available on the project website. Each document addresses a specific subject, while the collection provides a broader understanding of the responsibilities and practical challenges of healthcare engineering.

The content is educational. Its application in practice requires consideration of the conditions of each healthcare facility, the applicable standards and the instructions provided by equipment manufacturers.

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Health effects of stainless steels

1. Influence of alloying elements on the toxicity of stainless steels

According to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices [T1] "The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or other persons. The design must allow easy handling and, where necessary, reduce as far as possible contamination of, and leakage from, the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen. The manufacturing processes must be appropriate for these purposes". Let's first analyze the influence of the chemical composition of stainless steels on toxicity.

Chromium toxicity is associated with hexavalent chromium, that easily crosses biological membranes, interacting with protein components and nucleic acids within the cell before being deoxygenated to trivalent chromium. Hexavalent chromium's carcinogenic properties are derived from its reaction with genetic material [1]. Trivalent chromium is the most stable form of Cr found in living organisms. The most significant biological difference between it and hexavalent chromium is its inability to cross cell membranes and low reactivity. Trivalent chromium enters the body through the digestive tract and is necessary for the metabolism of carbohydrates, proteins and lipids [1]. Because chromium in stainless steels is in metallic form (with zero valence), its use in medical devices is not a health hazard.

Nickel plays an important role in human mineral balance, as nickel deficiency leads to reduced intrauterine growth and is also accompanied by reduced iron adsorption, which leads to anemia [2]. Like chromium, nickel enters the body through the digestive tract, as there are a lot of foods that contain Ni: spinach, cabbage, lettuce, peas, lentils, almonds, plums, dates, pineapple, buckwheat, oats, cocoa beans, soybeans, peanuts, walnuts, hazelnuts, dark chocolate, seafood (crab, oysters, shrimp, salmon) [2].

Manganese is a vital nutrient for both animals, humans and plants. Rocks, soil, water, and food all naturally contain manganese, that is involved in the formation of glycosaminoglycans, bone mineralization, protein and energy metabolism, metabolic regulation, and cellular defense against dangerous free radical species. Manganese functions as an enzyme activator as well as a component of metalloenzymes [3]. Consuming manganese-containing foods or supplements is the primary way that humans are exposed to manganese. Heavy tea drinkers and vegetarians who eat foods high in manganese, like grains, beans, and nuts, may consume more manganese than the average person. Some occupations, where manganese is inhaled in the form of dust or fumes (from welding or machining of steels), may increase the chances of nervous system or respiratory system damages caused by high manganese content. Manganese in solid state stainless steels is non-toxic and safe for everyday use [3].

Like manganese, in both plants and animals, including humans, **molybdenum** is an essential micronutrient. The dietary requirement for adults is 0.64 µg/kg body weight/day. Although these low levels of molybdenum are essential for human health, excessive exposure to environmental pollution, mainly industrial emissions, mining and steel processing, poses severe risks. Reduced body weight, kidney damage, decreased male fertility, and anemia after oral exposure to molybdenum trioxide appear to be the most sensitive disorders, as do respiratory effects after inhalation exposure. The majority of the general public's exposure to molybdenum comes from food. When compared to foods derived from tubers or animals, foods derived from surface plants, such as cauliflower, leafy vegetables, and legumes, typically have a higher concentration of molybdenum. The most abundant sources of molybdenum in the typical diet are beans, grains, leafy vegetables, legumes, liver, and milk [4]. Molybdenum in stainless steel, in its solid and stable alloy form, poses no health risks and is considered extremely safe for food, medical and everyday contact use.

2. Requirements for medical devices

Essential requirements designed to protect both patients and professional users are standardized in Europe in the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices [T2]. According to this Regulation “medical device means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Also medical devices are considered:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilization of medical devices".

According to this Regulation design and manufacture requirements for medical devices are:

- to select the materials and substances, particularly with respect to toxicity and, when applicable, flammability;
- to guarantee the materials' compatibility with biological tissues, cells, and body fluids, considering the device's intended use as well as, when relevant, metabolism, absorption, distribution and excretion;
- to ensure compatibility among implantable device components;
- to verify that processes do not affect the characteristics of the materials;
- to respect the results of previously proven biophysical or modeling studies, where applicable;
- to consider the mechanical properties of materials used, including strength, ductility, fracture toughness, wear resistance and fatigue resistance;
- to ensure adequate surface properties;
- to confirm that device meets any defined chemical and/or physical specifications.

Despite having adequate mechanical and biocompatibility qualities, stainless steel has some flaws on the implant surface, primarily because of its uneven microstructure. The bacterial response and cellular integration are greatly influenced by the surface characteristics of implants, including

chemical composition, surface roughness, wettability, electrical properties, and protein adhesion. Preventing bacterial adhesion is the primary concern for medical instruments and devices, whereas the surface of cardiovascular implants should not only prevent bacterial adhesion but also encourage the growth of endothelial cells, inhibit platelet adhesion and decrease the proliferation of smooth muscle cells. In the case of stainless steel used in orthopedic surgery, good proliferation of osteoblast cells (bone-forming cells) is very necessary to ensure the desired biocompatibility, even though bacterial adhesion is not desired (Figure 1). As a result, the surfaces need to be appropriately prepared for use in particular applications. Bacterial adhesion should always be stopped without affecting the intended biological reactions with other cells [5].

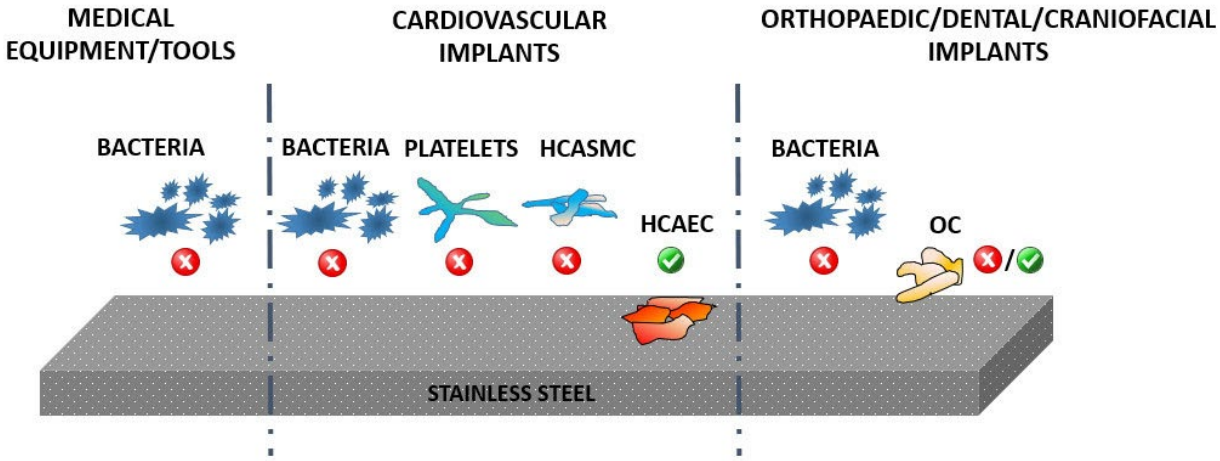


Fig. 1 Desired events that occur on the surfaces of stainless-steel biomaterials used for medical devices, cardiovascular implants, orthopedic, dental and craniofacial implants (HCAEC-human coronary artery endothelial cells, HCASMC-human coronary artery smooth muscle cells, OC-osteoblast cells) [5].

Compared to other metallic implants, stainless steel implants have been linked to higher infection rates because the material lacks intrinsic antibacterial qualities and frequently forms fluid-filled fibrous capsules at the interface between the implant and surrounding tissue, which provides the perfect conditions for bacterial colonization. In addition to preventing the intimate integration of an implant with the surrounding tissues, this can result in the formation of a biofilm that effectively shields the enclosed microorganisms from immune cells and antibiotics. This can also lead to the development of chronic infections, which can result in extended hospital stays, postoperative complications such as implant-associated infections, implant rejection, and, in severe cases, death.

A schematic representation of biofilm formation is shown in Figure 2. The stages of the process are: initial attachment (adherence) of microorganisms to the implant, permanent fixation onto the implant, formation of microcolonies and macrocolonies (because of maturation), and, finally, biofilm dispersion.

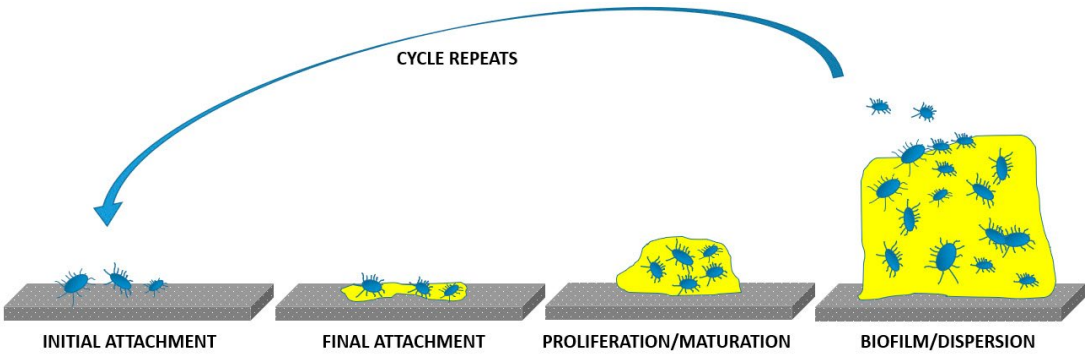


Fig. 2 Stages of biofilm formation on implant surfaces [5].

Several examples of the use of AISI 316 and AISI 316L stainless steels for medical devices are presented in [5] (Figure 3).

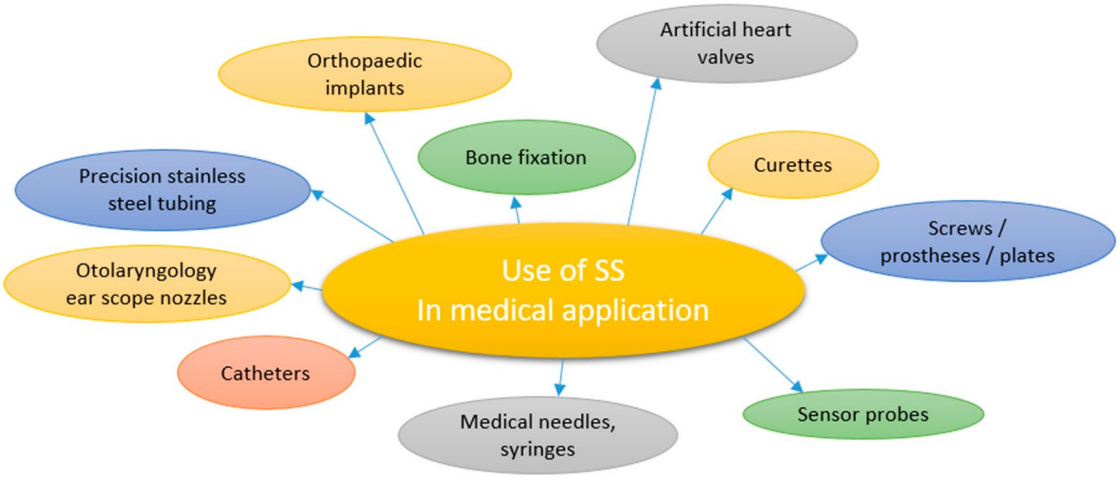


Fig. 3 Possible uses of stainless steel in medical devices [5].

3. Enhancing antibacterial activity of stainless steels

The antibacterial activity of stainless steel (SS) biomaterials can be enhanced by:

- changing the surface chemistry using antimicrobial substances added to inorganic or organic thin surface layers, coating with biochemical materials (calcium phosphate or hydroxyapatite), application of hardystonite nano-bioceramics using sol-gel and surface platinization;
- nanostructuring for breaking the microbial membrane that ensures cell adhesion through Laser surface texturing (LST), Laser-induced periodic surface structures (LIPSS) and nanocavitation;
- lowering water contact angle, ultrafine granular structure and suitable surface chemical composition;
- superficial microalloying with plasma.

Hydroxyapatite coating results in superior cell morphology and cell adhesion (Figure 4) but inhibits cell proliferation [6].

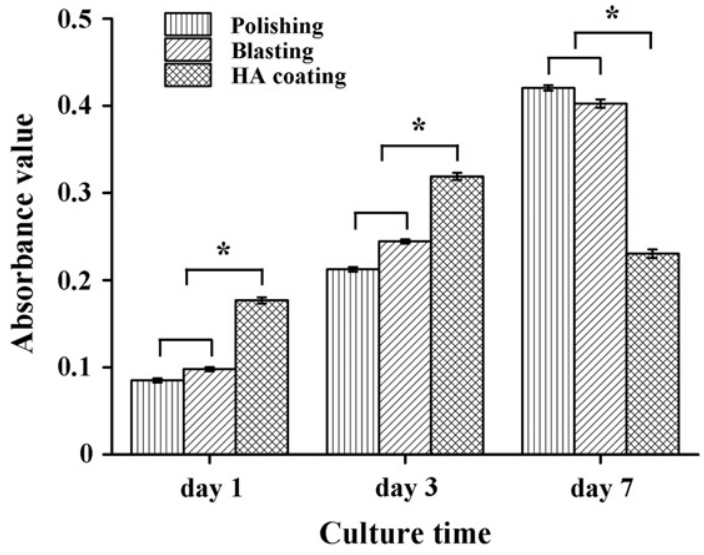


Fig. 4 Proliferation kinetics of MC3T3-E1 osteoblast-like cells on AISI 316L stainless steel samples polished, sandblasted, and hydroxyapatite (HA) coated after 1, 3, and 7 days of incubation [6].

Generating LIPSS (Laser-Induced Periodic Surface Structures) can reduce bacterial adhesion by modifying the surface topography at the nanoscale. By achieving an average structural periodicity of approximately 260 nm, bacterial adhesion was significantly reduced, by up to 43% for Staphylococcus aureus and up to 70% for Salmonella spp. [7].

In Figure 5, AFM images show that dimensions of the bacteria are larger than the periodicity of the LIPSS; this prevents the bacteria from penetrating the cavities and limits contact to the peaks only [7]. This reduced number of attachment points explains the decrease in adhesion and supports the use of LIPSS in antibacterial applications for medical devices and healthcare environments.

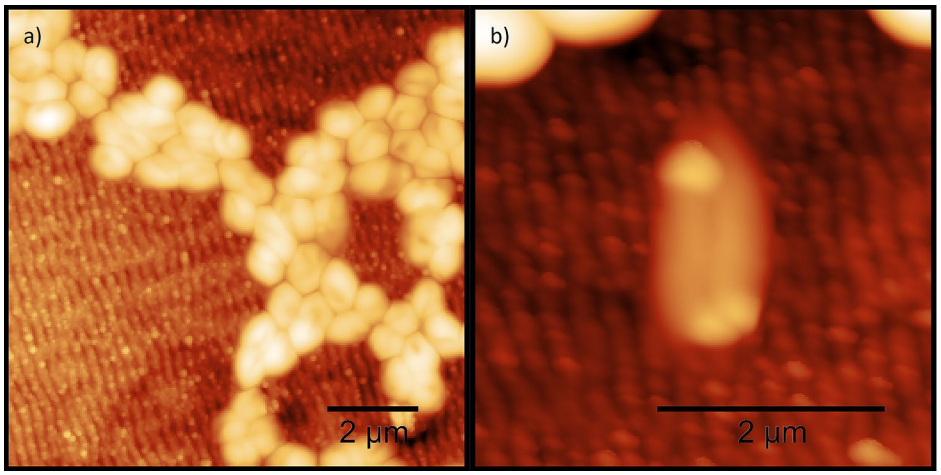


Fig. 5 AFM images of Staphylococcus aureus (a) and Salmonella spp. (b) on nanostructured surfaces with LIPSS on AISI 430 stainless steel [7].

In the case of Staphylococcus aureus adhesion, it was observed that the application of LIPSS reduces relative adhesion by an approximately constant amount as a function of the Surface Density of Applied Energy (SDAE). In the case of Salmonella spp. adhesion, the application of LIPSS with a higher surface density of applied energy results in a more pronounced reduction in relative adhesion [7].

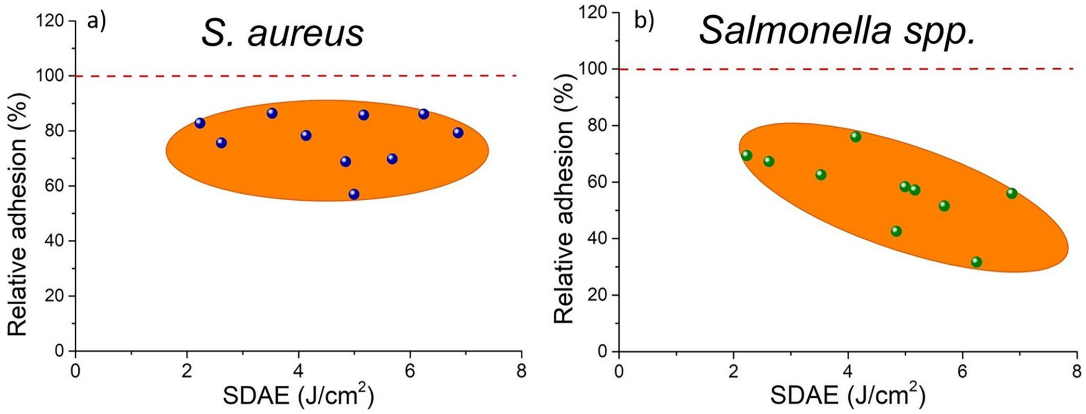
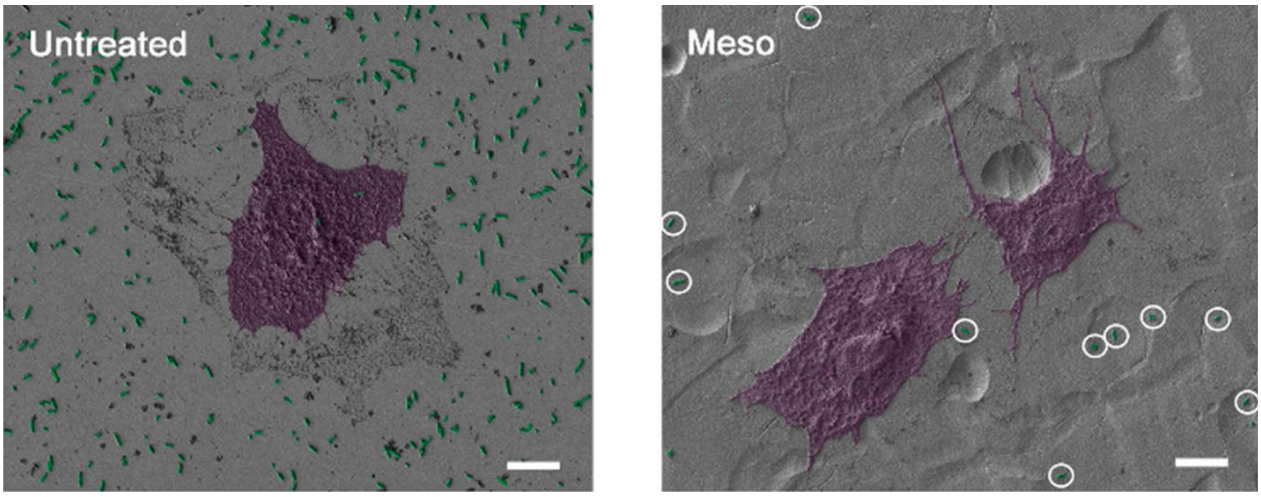


Fig. 6 Relative adhesion of Staphylococcus aureus (a) and Salmonella spp. (b) in stainless steel nanostructured surfaces with LIPSS in function of SDAE [7].

In [8], the surface of AISI 304 stainless steel was electrochemically anodized in an H_2SO_4 solution at a current density of 700 A/m². After 1 hour of incubation, a very small number of Escherichia coli bacteria had adhered to the nanotextured stainless steel surface, and this number remained virtually unchanged after 4 hours, indicating the absence of significant proliferation (Figure 7b). On the untreated surface of the stainless steel, the number of Escherichia coli bacteria increased substantially (Figure 7a).



(a) (b)

Fig. 7 The adhesion of Escherichia coli (green) and osteoblastic cells (purple) on the surface of untreated AISI 304 stainless steel (a) and electrochemically anodized AISI 304 stainless steel, 4 hours, bar = 10 μm (b) [8].

4. Review questions and suggested answers

Questions for independent study

1. What type of chromium is harmful to health?

2. In stainless steels chromium is a health hazard?

3. What disease does nickel deficiency cause?

4. What is the main concern regarding medical instruments and devices?

5. List three uses of stainless steel in medical devices.

6. List three methods for improving the antibacterial activity of stainless steels.

Answers

1. Hexavalent chromium has carcinogenic properties.

2. Not, because chromium in stainless steels is in metallic form (with zero valence.

3. Nickel deficiency reduces iron adsorption, which leads to anemia.

4. Preventing bacterial adhesion is the primary concern for medical instruments and devices.

5. Medical needles, catheters, orthopaedical implants, artificial heart valves.

6. Coating with biochemical materials, Laser surface texturing (LST), Laser-induced periodic surface structures (LIPSS), nanocavitation

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Standards and technical reading

[T1] Directive 98/79/EC of the European parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

[T2] Regulation (EU) 2017/745 of the European parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

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