НИИ МЕДИЦИНСКИХ МАТЕРИАЛОВ И ИМПЛАНТАТОВ С ПАМЯТЬЮ ФОРМЫ Сибирского физико-технического института при Томском государственном университете

МАТЕРИАЛЫ С ПАМЯТЬЮ ФОРМЫ И НОВЫЕ ТЕХНОЛОГИИ В МЕДИЦИНЕ



SURFACE CHARACTERS AND BIOCOMPATIBILITY OF TI-NI SHAPE MEMORY BIOMEDICAL MATERIALS Kim Ji-Soon, Kang Seung-Baik, Park Don-Kyu, Gjunter V.E.

Abstract. A brief review on the scientific reports regarding the surface characters and the biocompatibility of Ti-Ni shape memory biomedical materials is given, most of which confirm the superior properties of Ti-Ni materials in comparison with other conventional ones.

Introduction. TiNi is the most commercially successful shape memory alloy (SMA) and is already in use in the biomedical, aerospace, and automotive industries. TiNi alloys are important materials for biomedical and dental devices because they offer excellent biofunctionality related to their unique properties like pseudoelasticity, shape memory effect, damping capacity, high corrosion-resistance, and deformation compatibility of TiNi with living tissues. Current biomedical applications that take advantage of these properties include stents for peripheral procedures, orthodontic arch wires, microactuators, surgical tools, staples, clot filters, and many others [1, 13, 40].

Recent in vitro studies [2, 3] as well as in vivo assays [4, 5] showed very promising biological behavior for TiNi. However, despite these results and many successful clinical applications of TiNi [6] the biocompatibility of this alloy still remains controversial because of the high content of Ni, which apparently limits a wider medical use of TiNi. Some literatures showed in fact that nickel toxicity exists in some special case [7]. Recently, many studies have been devoted to the surface and biocompatibility investigation of TiNi [8–16] to confirm the effectiveness of TiNi compared with other commercially used implant metals like pure Ti, Ti-alloys, Co-alloys, and stainless steels whose surface properties are relatively well known.

In this article some of scientific works on the surface characters and biocompatibility of TiNi shape memory alloy are briefly summarized and their lists are given for further informations.

Surface Character and Corrosion Resistance of TiNi. Even though the protective oxide film exists on the metal surface, metal ions can still be released through corrosion processes. The release of metal ions may have adverse biological effects, depending on the ion species and its concentration. Although some of works have reported that the biological side effects of Ni can be also available [17–20], many other works are reporting no toxic effect of TiNi alloy [21–22].

The good corrosion resistance of TiNi results from the formation of very stable, continuous, highly adherent, and protective oxide films on its surface. Because titanium is highly reactive and has a high affinity for oxygen, these beneficial surface oxide films form spontaneously when fresh metal surfaces are exposed to air and/or moisture. In fact, a damaged oxide film can generally reheal itself if at least traces of oxygen or water (moisture) are present in the environment [23]. In addition, calcium-phosphate surface films can be naturally formed in a biological environment [24–26], which can act as a further barrier against ion diffusion from the subsurface alloy. In comparison with 316L stainless steel, TiNi alloys has been known to exhibit equivalent, or even better corrosion resistance [27–29]. Various processes have been to improve the corrosion resistance of TiNi by surface treatment such as electropolishing, heat treatment and ion implantation [30–31].

Results from the investigation on the surface of TiNi using SEM, EDS, XPS and Auger [32, 33] showed that, in fact as with pure titanium, the passivation film present on Ni-Ti is mainly constituted of TiO_2 and actually, the excellent biocompatibility of TiNi has been attributed [32–34] to the TiO₂-based oxides passivation film.

Biocompatibility. The biocompatibility of any biomaterial is related to the implant-body interactions and for metallic implants it is directly related to the nature of their surface at the beginning of and during the implantation. The chemical nature, the roughness, and the surface energy are parameters that will define implant biocompatibility.

Vandenkerkhove and coworkers [35] reported from the literature data that the biocompatibility is often contradictory; nevertheless, they affirmed that no severe damage has been found in living tissue in direct contact with Ni-Ti. In a paper appearing in the 1970s, Castelman and coworker [36] concluded that the biocompatibility of Ni-Ti was sufficient to promote study of possible applications. More recent reviews [37–38] show a favorable picture of the biocompatibility of Ni-Ti. Shabalovskaya [39] and Van Humbeek and coworkers [33] stated that the biocompatility of Ni-Ti is comparable with that of stainless steels, Co-based alloys, and titanium alloys. Ryhanen [37] concluded that it is similar to or better than stainless steel and Ti-6Al-4V.

Conclusion. Many of research works prove that TiNi shape memory materials have excellent corrosion resistance and biocompatibility, biologically and mechanically. A great number of clinical cases of various medical fields in Russia and China are the real evidence showing the effectiveness of TiNi materials for the biomedical application.

References

1. Stoeckel D. TiNinol medical devices and implants, Minim. Invasiv. Ther., 2000;9(2):81-8.

2. Assad M., Yahia L.'H., Rivard C.H., Lemieux N. In vitro biocompatibility assessment of a nickel-titanium alloy using electron microscopy in situ end labeling (EM-ISEL) // J. Biomed. Mater. Res. 1998;41:154–161.

3. Wever D.J., Veldhuizen A.G., Sanders M.M., Schakenraad J.M., Van Horn J.R. Cytotoxic, allergic and genotoxic activity of a nickel-titanium alloy. Biomaterials 1997;18:1115–1120.

4. Trepanier C., Leung T.K., Tabrizian M., Yahia L.'H., Bienvenu J.G., Tanguay J.F., Piron D.L., Bilodeau L. Preliminary investigation of effects of surface treatments on biological response to shape memory TiNi stents // J. Biomed. Mater. Res. 1999;48:165–171.

5. *Ryhaenen J., Kallioinen M., Tuukkanen J., Junita J., Niemela E., Sandvik P., Serlo W.* In vivo biocompatibility evaluation of nickeltitanium shape memory metal alloy: muscle and perineural tissue responses and encapsule membrane thickness // J. Biomed. Mater. Res. 1998;41:481–488.

6. Dai K., Chu Y. Studies and application of TiNi shape memory alloys in the medical field in China. Biomed. Mater. Eng. 1996;6(4):233-240.

7. Grimme P., Hupfer P. Auswirkungen auf die Erzeugung und Verwendung nickelhaltiger Produkte (Consequences of manufacture and application of nickel-containing products) // Metallurgy. 1992;46(4):365–9 (in German).

Villermaux F., Tarbizian M., Yahia LH., Meunier M., Piron D.L. Excimer laser treatment of TiNi shape memory alloy biomaterials.
Appl. Sci. 1997;109/110:62–6.

9. Shabalovskaya S.A. On the nature of the biocompatibility and on medical applications of TiNi shape memory and superelastic alloys // Bio-Med. Mater. Eng. 1996;6:267–89.

10. Oshida Y., Sachdeva R.C.L., Miyazaki S. Microanalytical characterization and surface modi"cation of TiNi orthodontic archwires // Bio-Med. Mater. Eng. 1992;2:51–69.

11. Green S.M., Grant D.M., Wood J.V. XPS characterization of surface modified Ni-Ti shape memory alloy // Mater. Sci. Eng. 1997; A224:21-6.

12. Shabalovskaya S.A. Biological aspects of TiNi alloy surfaces // J. Phys. 1995;5:1199-204.

13. Гюнтер В.Э., Котенко В.В., Миргазизов М.З. и др. Сплавы с памятью формы в медицине. Томск: Изд-во Том. ун-та, 1986. 208 с. (in Russian).

14. Miyazaki S. Surface and interface of shape memory alloys // Surf. Sci. 1994;15:467-72.

15. Castellman L.S., Motzkin S.M. The biocompatibility of TiNinol / Williams D.F., editor. Biocomparibility of clinical implant materials, vol. 1. Miami F.L.: CRC Press, 1982. p. 145–50.

16. Zhuk Y.N. Advanced medical applications of shape memory implants in Russia. TETRA Consult, Moscow State University, Moscow, 1994.

17. McKay G.C., Macnair R., MacDonald C., Grant MH. Interactions of orthopaedic metals with an immortalized rat osteoblast cell line // Biomaterials. 1996;17:1339-44.

18. Kerosuo H., Kullaa A., Kerosuo E., Kanerva L., Hensten-Petterson A. Nickel allergy in adolescents in relation to orthodontic treatment and piercing of ears // Am. J. Orthod. Dentofac. Orthop. 1996;109:148–54.

19. Berger-Gorbet M., Broxup B., Rivard C., Yahia L'.H. Biocompatibility testing of Ni-Ti screw using immuno histochemistry on sections containing metallic implants // J. Biomed. Mater. Res. 1996;32:243–8.

20. Bass J.K., Fine H., Cisnero G.J. Nickel hypersensitivity in the prosthodontics patient // Am. J. Orthod. Dentofac. Orthop. 1993;103:280-5.

Grimsdottir M.R., Hensten-Pettersen A., Kulmann A. Cytotoxic effect of orthodontic appliances // Eur. J. Orthod. 1992;14:47–53.
Ryhanen J., Niemi E., Serlo W., Niemela E., Sandvik P., PernuH., Salo T. Biocompatibility of nickel-titanium shape memory metal and its corrosion behavior in human cell cultures // J. Biomed. Mater. Res. 1997;35:451–7.

23. Stone P., Bennett R.A., Bowker M. Reactive re-oxidation of reduced TiO2 (1 1 0) surfaces demonstrated by high temperature STM movies. New J. Phys. 1999;1:1–12

24. Hanawa T., Ota M. Calcium phosphate naturally formed on titanium in electrolyte solution // Biomaterials. 1991;12:767–76.

25. Hanawa T. In vivo metallic biomaterials and surface modification // Mater. Sci. Eng. A 1999;267:260-6.

26. Demri B., Hage-Ali M., Moritz M., Muster D. Surface characterization of C/Ti-6Al-4V coating treated with ion beam // Biomaterials. 1997;18:305-10.

27. Venugopalan R., Tr!epanier C. Assessing the corrosion behaviour of TiNinol for minimally invasive device design // Minim. Invasiv. Ther. 2000;9(2):67–74.

28. Wever D.J., Veldhuizen A.G., de Vries J., Busscher H.J., Uges D.R.A., van Horn J.R. Electrochemical and surface characterization of a nickel-titanium alloy // Biomaterials 1998;19:761–9.

29. Rondelli G., Vicentini B., Gigada A. The corrosion behavior of nickel titanium shape memory alloys // Corrosion Sci. 1990; 30(8–9):805–12.

30. Trepanier C., Tabrizian M., Yahia L.H., Bilodeau L., Piron D.L. Effect of Modification of Oxide Layer on TiNi Stent Corrosion Resistance // J. Biomed. Mater. Res. 1998;43: 433–440

31. Tan L., Dodd R.A., Crone W.C. Corrosion and wear-corrosion behavior of TiNi modified by plasma source ion implantation // Biomaterials. 2000;24: 3931–3939.

32. Shabalovskaya S.A., Anderegg J.W. Surface spectroscopy characterization of TiNi nearly equiatomic shape memory alloy for implants // J. Vac. Sci. Technol. A 1995;13:2624–2632.

33. Van Humbeek J., Stalmans R., Besselink P.A. Shape memory alloy // Metals as biomaterials / Helsen A., Breme HJ., editors. Chichester, England: Wiley, 1998. p 73–100.

34. Wever D.J., Veldhuizen A.G., De Vries J., Busscher H.J., Uges D.R.A., van Horn J.R. Electrochemical and surface characterization of nickel-titanium alloy // Biomaterials 1998;19:761–769.

35. Vandenkerckhove R., Temmerman E., Verbeeck R. Electrochemical research on the corrosion of orthodontic nickeltitanium wires // Mater. Sci. Forum. 1998;289–292:1289–1298.

36. Castelman L.S., Motzkin S.M. The biocompatibility of TiNinol // Biocompatibility of clinical implant materials / Williams D.F., editor. Vol. I. Boca Raton, F.L: CRC Press, 1981. p 129–155.

37. Ryhanen J. Biocompatibility evaluation of nickel-titanium shape memory metal alloy // Academic dissertation. University of Oulu, Finland, 1999.

38. Oshida Y., Miyazaki S. Corrosion and biocompatibility of shape memory alloys // Corrosion Eng. 1991;40:1009–1025.

39. *Shabalovskaya S.A.* On the nature of the biocompatibilty and on medical applications of TiNi shape memory and superelastic alloys // Biomed. Mater. Eng. 1996;6:267–289.

40. Gunter V.E., Dambaev G.Ts., Sysolyatin P.G. et al. Delay law and new class of materials and implants in medicine. Northampton, MA: STT, 2000. 432 p.