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Status of nickel free stainless steel in biomedical field: A review of last 10 years and what else can be done

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ABSTRACT

The area of biomaterials is a continuous research area. Among others, stainless steels are also used in medical applications such as fracture plates, wires, sutures and implants etc. Surgical grade 316 L stainless steel is specifically used for medical application. It primarily contains nickel, chromium and molybdenum wherein the purpose of nickel is to retain the FCC structure of stainless steel almost at any temperature unlike conventional steel which has ferrite (BCC structure) in ambient temperature. Also, nickel imparts a polished and glossy finish to surgical grade stainless steel which is an important factor to keep it hygienic. But, the harmful effect of nickel on human body has been investigated and reported for quite some time now. The adverse effect of nickel (Ni) ions that release from stainless steel upon crevice and pitting corrosion has led to the evolution of Ni-free stainless steel with high nitrogen content. This paper briefly reviews the effect of nickel release in human body and let go the presence of nickel in stainless steel by uplifting nitrogen content in it. Furthermore, the groundbreaking findings on Ni-free stainless steel in last 10 years are presented and the possibilities of further developments have been hypothesized.

Selection and of the scientific committee of the 10th International Conference of Materials Processing and Characterization.

1. Introduction

Metals are predominantly used as implants in biomedical industries. The foremost criterion for choosing any implant material is its biocompatibility. The reason for choosing metallic implant is its superior mechanical strength and corrosion resistance. The most commonly used biomedical alloys are grade 5 Ti6Al4V, CoCrMo and stainless steel (AISI 316L) [1,2]. The fabrication of stainless steel is comparatively easier than Ti-alloys and Co-Cr alloys. Although stainless steel is used as implants at places but its application is confined to bone healing, screws and fixations.

Stainless steel is present in three microstructures which are austenite, martensite and ferrite. There is one other kind which is the duplex stainless steel; it basically contains both austenite and ferrite structure [3]. These structures are attributed to proper adjustments in its chemistry which later reflects in its properties. For instance, austenitic steel doesn't possess ferromagnetism properties like its counterpart martensitic and ferrite steel. One of the preferential attribute of implants is the non-existence of ferromagnetic property which is why austenitic stainless steels are preferred over martensitic and ferrite steels for implant material. The other advantages of austenitic steels are their FCC structure, low yield strength to tensile strength ratio, better formability and corrosion resistance among others. 316 L Stainless steel is basically Fe-based alloys containing carbon (C of maximum 0.03%), chromium (Cr of atleast 16%) and nickel (Ni of atleast 10%). Homogenous corrosion resistance is the most important characteristics of stainless steel. Corrosion resistance is not an intrinsic property but the behavior of material surface in interaction with environment. Indeed, corrosion resistance is developed in stainless steel by the formation of passive surface film which acts as a blockade between the surface and the surrounding environment. Stainless steel doesn't possess hexavalent chromium; instead, chromium is present in metallic form i.e. in zero valency state. Nonetheless, stainless steel has got bad reputation in body fluid condition for pitting, intergranular, crevice and fretting corrosion [4,5] which ultimately succumbs the implant to fail. Not to forget that corrosion of any kind is responsible for release of various harmful metallic ions which has adverse effect on human body and one of such candidate is nickel ions [6,7]. Before getting into

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nickel and the problems associated with it, the applications of 316 L stainless steel and its contemporaries such as Ti-alloys and CoCr alloys in various aspects of biomedical field is briefed in Table 1.

1.1. The essential negative character of nickel

As discussed earlier, stainless steel is susceptible to localized corrosion and to many people's concern; nickel is about 12 to 15% in stainless steel. There are reports of nickel being responsible for mutagenic and genotonic activities, eczema, itching on skin and sometime cancer [8–11]. As stainless steel starts to corrode, the release of metallic ions starts to interact with proteins in the body, a process known as haptenization. This interaction further develops hyper sensitive reactions. To start with, the very first allergic reaction reported over a stainless steel fractured plate was described to an eczematons rash [12]. Then after, many such issues were reported and documented when patients suffered swelling, erythema and problems associated with skin in the periphery of the implant. Some patients also witnessed soreness and weakness in general [13]. Although nickel is an essential element for human functionality but excess of it in the body causes health related problems. In addition to it, chronic exposure which leads to higher accumulation of nickel has reported to cause cardiovascular problems and lung fibrosis [14]. Experimental investigations suggest that higher nickel intake in body has carcinogenic and teratogenic potential. For example, nickel is toxic to cardio vascular muscles when its concentration is above 11.7 ppm. The International Agency for Research on Cancer (IARC) has pronounced nickel compounds to be carcinogenic to humans [15].

It has been reported that number of women who are affected from nickel are doubling with every passing year. As per the assumption made by dermatologists across globe, it is said that around 20% of young women and 4% of young men are directly or indirectly have allergies caused due to nickel which is indicated in Fig. 1 [16].

Considering the adverse effect of nickel on human body, it is of utmost priority to avoid excessive nickel into human body. And to cater that, nickel free stainless steel was developed without compromising the preferential characteristics of any biomedical alloy such as good biocompatibility, mechanical strength, corrosion resistance, non-ferromagnetic and wear resistance among others. This paper deals with the perilous effects of nickel in human body, evolution of Ni-free high nitrogen stainless steel (Ni-free HNS), recent findings in last 10 years and possible windows for further development in it.

2. Nickel free austenite stainless steel

Development of Ni-free stainless steel has been carried out over the years. Ni-free martensitic and ferrite stainless steel are ferromagnetic in nature but not austenitic ones. In this, nickel is substituted by nitrogen or manganese or both. Fig. 2 illustrates the modified Schziffer diagram where the direction of development of Ni-free stainless steel is indicated [17]. It is a known fact that high nitrogen stainless steel can be produced with conventional melting process that includes ferrite steel with 0.08 wt% and austenitic steel with 0.4 wt% nitrogen [18]. It is both biocompatible and corrosion resistant, plus it retains austenitic microstructure. It has showcased better mechanical and fracture properties as well which to many researchers can be an alternate to AISI 316L stainless steel for medical applications [19].

Table 1
Biomedical application of stainless steel and its contemporaries.

Applicable area	Implant type	Biomedical alloys
Otorhinology	Artificial eardrum	316 L stainless steel
Cardiovascular	Stent	316 L stainless steel, Ti6Al4V, CoCrMo, Ti6Al7Nb
Craniofacial	Plates and screws	316 L stainless steel, Ti6Al4V
Orthopaedic	Artificial joints, bone fixation	Ti6Al4V, CoCrMo, 316 L stainless steel
Dentistry	Filling, orthodontic wire	AgSn (Cu) amalgam, TiNi, 316 L stainless steel

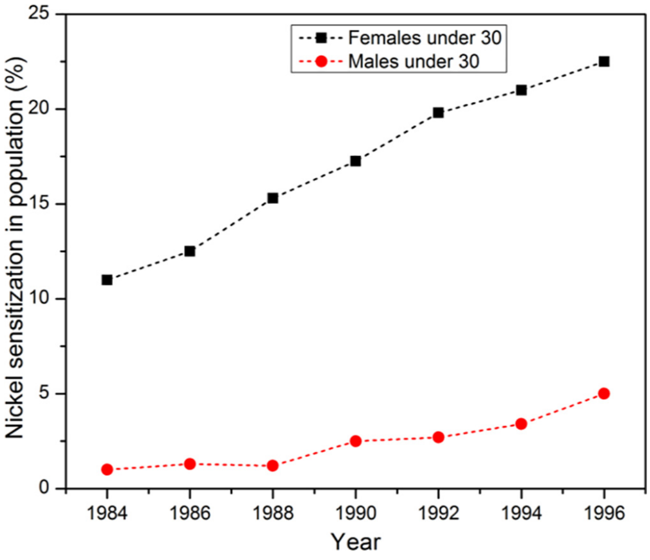

Fig. 1. Percentage of population sensitized to nickel allergy [16].

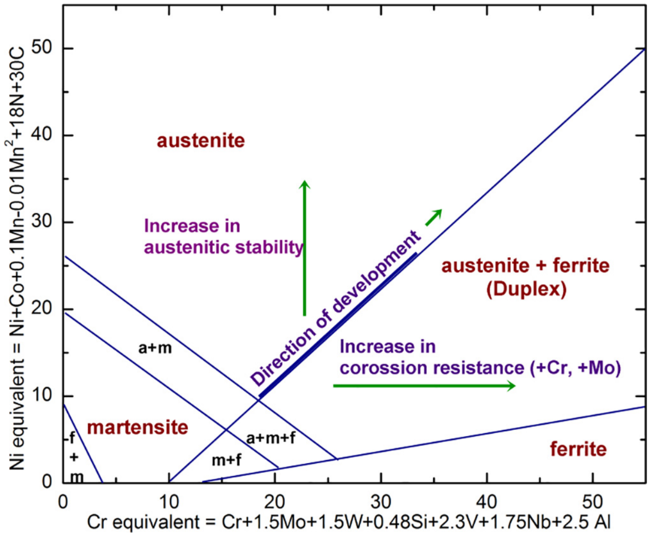

Fig. 2. Development of Ni-free stainless steel presented in Schziffer diagram [17].

The most commonly used techniques to achieve high nitrogen steel (HNS) are electroslag melting, plasma arc melting, induction furnace and powder metallurgy etc. Some of the developments in this regard are mentioned below.

- P558 is a newly developed alloy with high concentration of manganese and nitrogen and nickel content as low as <0.02%. It exhibits excellent wear resistance, high strength and hardness.

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- Biodur 108 alloy (Carpenter Technology Corporation), Fe-23Cr-23Mn-1Mo-0.9 N has showcased enhanced yield strength of 606 MPa in annealed condition as compared to 241 MPa yield strength of AISI 316L stainless steel.
- BIOSSN4 steel (Institute of Metal Research, CAS), 18Cr-15Mn-2Mo- (0.45–0.7)N has exhibited better wear resistance and biocompatibility. It has yield strength and ultimate tensile strength (UTS) 2–3 times higher than AISI 316L stainless steel.

The chemical composition and mechanical properties of newly developed Ni-free stainless steel are tabulated in Tables 2 and 3 respectively. Furthermore, Walter el al [20] has demonstrated that BioDur 108 has similar behavior towards corrosion to that of BioDur 734 and 22Cr-13Ni-5Mn alloy but performs well compared to traditional BioDur 316LS. Also, BioDur 108 has greater range of yield strength compared to BioDur stainless steel alloys as shown in Fig. 3.

3. Role of nitrogen

3.1. Its effect on corrosion resistance and biocompatibility

Nitrogen is considered to be a significant alloying element in stainless steel in terms of its performance in corrosive environment. Its role is vital in the stability of the passive layer for resistance towards pitting, intergranular and crevice corrosion [21,22]. Literature suggests that nitrogen aids in the widening of passive layer which reduces the chances of pitting and crevice corrosion [23].

Baba et al. [24] reported that nitrogen on dissolving in austenitic steels increases resistance to crevice corrosion in chloride environment. (See Fig. 4(a)). Sakamoto et al. [25] demonstrated that with increasing level of nitrogen in 25Cr16Ni5Mo2cu enhances its resistance to crevice corrosion in ferric chloride solution. Amuza et al. [26] reported that higher nitrogen concentration is effective for resistance to corrosion because it forms a passive layer of ammonium ions that decreases the proliferation of corrosion at the crevice site. Fig. 4(b) shows that with increase in nitrogen content from 316 L (0%N) to 316LN (0.151%N), the pitting potential increases. The decrease in passive current and increases in pitting potential with increase in nitrogen concentration is ascribed to the formation of more substantial passive layer due to nitrogen alloying [27].

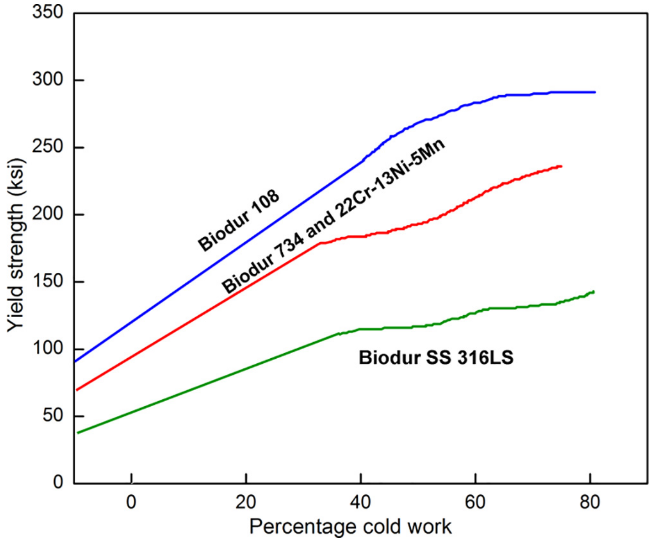

Fig. 3. Yield strength of various BioDur stainless steel alloys [20].

HNS is considered to be an alternate to 316L stainless steel because of its noble biocompatibility [28]. Akiko et al. [29] has reported higher cell growth in Fe-Cr-Mo-N than 316L and Ni-free ferrite steel in both static and dynamic condition during cytocompatibility test. Similar observation was demonstrated by Ma et al. [30]. They found that cell growth in HNS was higher than 317L stainless steel indicating higher cytocompatibility of HNS. Fig. 5 (a) shows the cytotoxicity of 316L stainless steel, Fe-Cr-Mo and Fe-Cr-Mo-N under worn out condition.

Kinetic clotting time is an indicator of how quickly the blood clots when it comes in contact with a material surface. It is evident from Fig. 5(b) that optical density of the blood decreases quickly when it comes in contact with 317L stainless steel while with Ni-free HNS, it decreases slowly [31].

4. Status of Ni-free stainless steel in last 10 years

Table 4.

Table 2
Chemical composition of newly developed Ni-free stainless steel.

Stainless steel	%C	%Cr	%Mn	%Mo	%Si	%Ni	%N	%Cu
BIOSSN4	0.043	17.9	15.3	2.02	0.02	0.2	0.46	0.66
PANACEA P558	0.2	17.4	10.18	3.09	0.43	0.08	0.48	–
24Cr-2Mo	–	24	–	2	–	–	1.0	–
BioDur 108	0.08	21	23	0.7	0.75	0.3	0.97	0.25
24Cr-1N	–	24	–	–	–	–	1.0	–
X13CrMnMoN18	0.13	18	14	3	–	0.05	0.75	0.25

Table 3
Mechanical properties of newly developed Ni-free stainless steel.

Stainless steel	σ_y	UTS	Elongation (%)	Hardness (Hv)
BIOSSN4	559	938	54	248
PANACEA P588	600	923	54	367
24Cr-2Mo	–	1167	45	–
BioDur 108	586	931	52	–
24Cr-1 N	–	1032	26	–
X13CrMnMoN18-14–3	590	1030	70	259
SS 316L	220–260	500–540	55–65	130–160

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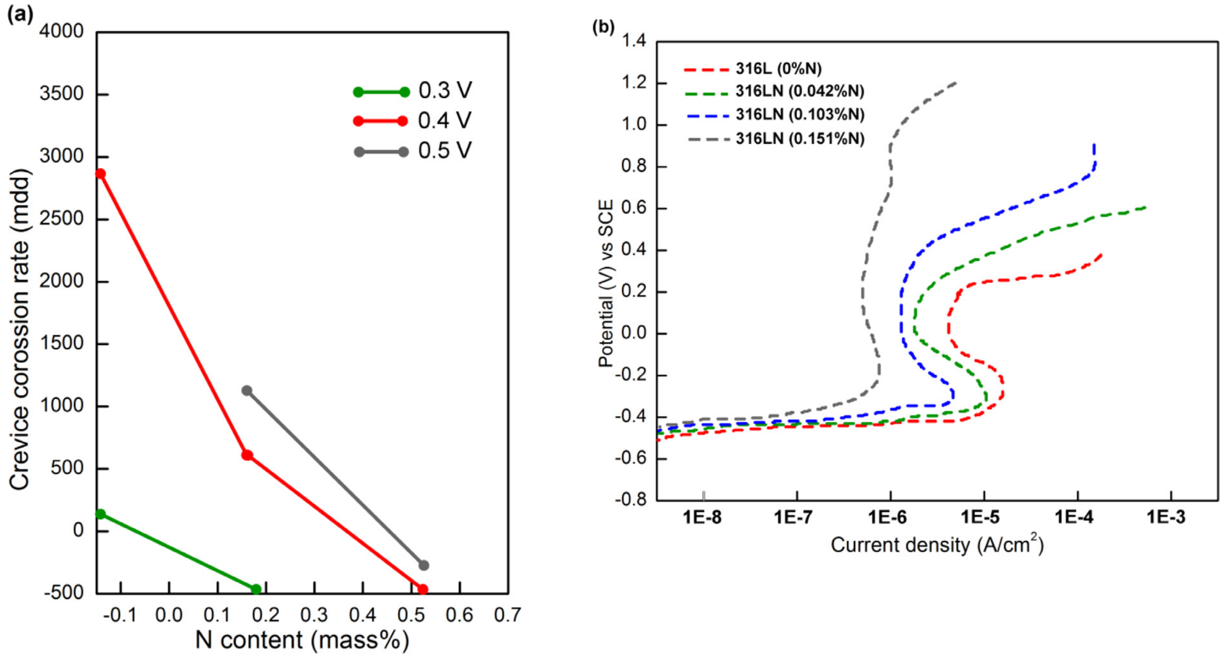

Fig. 4. Effect of nitrogen content in (a) crevice corrosion rate [26] and (b) potentiodynamic polarization [27].

Table 4
Developments in Ni-free stainless steel in last 10 years.

Sl No.	Year	Author	Materials	Methods	Findings
1.	2009	Hua-Bing et al. [32]	Ni-free HNS	Hot rolled HNS was given solution treatment at 1100C for 60 min and quenched	Ductility reduced and hardness increases with decreasing grain size.
2.	2009	Maria et al. [33]	Ni-free HNS	316L stainless steel, recycled and Ni-free stainless steel samples were immersed in artificial saliva of various pH values (4.2, 6.5, 7.6) and over different interval of time (0.25 h, 1 h, 24 h, 48 h and 120 h)	Ni-free stainless steel has the least release of chromium ions compared to others. It was 0.21 ± 0.51 μg/g for Ni-free stainless steel and 0.27 ± 0.38 μg/g and 0.52 ± 1.088 μg/g for recycled and 316L stainless steel.
3.	2011	Wan et al. [34]	Fe-17Cr-15Mn-2Mo (0.5–1.0)N	Biocorrosion study of Ni-free stainless steel compared to AISI 317L in PBS, PBS + albumin, PBS + fibrogen simulated body fluids	Lower capacitance and higher charge transfer resistance with increase in nitrogen content. Biocorrosion is Ni-free stainless steel was lesser than AISI 317L.
4.	2011	Ortiz et al. [35]	Stainless steel, Ni-free stainless steel, Ti-alloys	10 samples from each type were submerged in 0.5% fetal bovine serum and kept in a cell incubator	Cultured fibroblast in stainless steel was 0%, Ni-free stainless steel has the least release of ions. The greatest damage in DNA was reported in stainless steel followed by Ni-free stainless steel.
5.	2012	Ma et al. [36]	Ni-free HNS and AISI 317L	Cytocompatibility test of HNS and AISI 317L was performed. The samples were solution treated at 1353 K for 60 min	HNS showcased better cell growth and adhesion. Surface energy of HNS increased with increasing nitrogen concentration.
6.	2013	Erisir et al. [37]	DIN EN 1.4452	Study of hot deformation behavior using Thermo-Calc software	Optimum hot deformation was recorded in 1323 K to 1523 K temperature range.
7.	2013	Erfan et al. [38]	Medical grade stainless steel and Ni-free HNS	Samples were prepared using powder metallurgy. Electrochemical behavior was studied in SBF (pH value 7.4)	Pitting corrosion was lower in Ni-free HNS.
8.	2013	Cui et al. [39]	0Cr-17Mn-11Mo-3 N	Samples were prepared using powder injection moulding. Sintering optimization was performed	Sintering temperature was suggested to be the most important parameter, With increase in temperature, mechanical properties enhances but nitrogen content decreases.
9.	2014	Chao et al. [40]	Fe-16Cr-Mn-Mo-N	Corrosion test was conducted using potentiostat (EG & G263A) immersed in NaCl solution. The composition was analyzed using ICP-AES	Stable Cr_2O_3 passive film was formed which causes decrease in corrosion. Increase in the manganese content in HNS exhibited less resistance to corrosion.
10.	2015	Berezovskaya et al. [41]	06Kh18AG19M2 (0.81%N)	Hot plastically deformed samples were pressed in equichannel angular pressing with 120C intersection angle	The hardness of the steel doubles after during the treatment. Twinning and dislocation slip were observed in the samples.
11.	2015	Shao et al. [42]	Fe-18Cr-18Mn-0.63N	Samples were electropolished before fatigue test performed on the Instron 8801 servo hydraulic testing rig	Crack initiation starts at lower amplitude along the slip band, grain boundaries and twin boundaries.
12.	2016	Vashistha et al. [43]	E308, E309, E310	Hot rolled, milled samples were annealed at 1050C for 60 min followed by water quenching. The microstructure was studied using XRD	111, 200, 220 peaks confirms γ-austenite and manganese acted as a stabilizer. It is seen that δ-Fe was decreased.

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Table 4 (*continued*)

Sl No.	Year	Author	Materials	Methods	Findings
13.	2016	Li et al.[44]	Ni-free HNS	Samples were annealed at 1080C for 60 min followed by water quenching before electrochemical measurement using a potentiometer	In the presence of *P.aeruginosa* film on the surface, the corrosion accelerated in Ni-free HNS.
14.	2016	Zhao et al. [45]	NFHNSS	Samples were annealed at 1150C for one hour followed by water quenching and cold rolling at RT. Cyclic polarization test was performed in a potentiostat. Wear test was also performed	The structure was austenite with no evidence of strain-induced martensite. Corrosion resistance remained same after cold rolling. Abrasive wear mechanism was observed during wear test.
15.	2017	Sun et al. [46]	Ni-free HNS	Tensile test	The sample showcased two stage strain hardening behaviour.
16.	2018	Qlao et al. [47]	Ni-free HNS	Graphical abstractCavitation tests were conducted in 0.5 mol/L HCL and distilled water solution at 25 °C in Sonicator XL 2020	The corrosion potential of HNS shifted in positive direction. The dominant factor of CE damage was the mechanical attack.
17.	2018	Naik et al. [48]	Ni-free HNS	PMEDM of Ni-free stainless steel using TOPOSIS method.	Optimum setting for higher MRR and lower TWR at OC was obtained at 6 A peak current and 10 μs pulse on time at 3 g/lt powder concentration.
18.	2019	Zhang et al. [49]	Cold rolled Ni-free HNS	Nanoindentation and creep test at a loading rate of 100 μN/s to peak load of 600 μN and held constant for 1200 s	Creep deformation, creep stress and creep strain were observed to develop in cold rolled HNS.
19.	2019	Yang et al. [50]	HNNFS, 316L stainless steel	Samples were treated with water for 60 min at 25 °C, 50 °C, 75 °C and 95 °C and at 95 °C for 10 min, 60 min, 300 min and 600 min in nitric acid solution	The corrosion rate of HNNFS was reduced to 1/20 of the untreated HNNFS and 1/3 of 316 L stainless steel.
20.	2019	Ren et al. [51]	Ni-free HNS	Biomechanical study and finite element analysis of light weight Ni-free HNS fracture plate	Ni-free HNS has better strength and fixation ability than 316L stainless steel to accelerate healing of the femur bone. Ni-free HNS plate with 18% less thickness is showcasing same mechanical properties of 316L stainless steel.
21.	2019	Ibrahim et al. [52]	Ni-free HNS	Amorphous metallic glass cladding on Ni-free HNS	Hardness of the sample is 1300 Hv (around 6 times more) than 316L stainless steel

5. Further possibilities with Ni-free stainless steel

There is enough literature to suggest that Ni-free HNS exhibit least release of metal ions compared to 316L and 317L stainless steel. But still its usability is restricted in implant applications for the reason it has much higher modulus of elasticity compared to traditionally used grade-5 Ti6Al4V. For an instance, modulus of elasticity of femur bone is around 12 GPa and metallic alloys such as Ti6Al4V and CoCrMo alloy have 110 GPa and 225 GPa respectively. It can be clearly seen that Ti6Al4V has closer modulus of elasticity to bone's modulus of elasticity followed by stainless steel and CoCr alloys, so Ti6Al4V has a clear advantage over the other alloys in this regard. Implant material with higher modulus of elasticity accelerate stress shielding effect in the femur bone [53,54]. One of the possible works that can be carried out is increasing the porosity of Ni-free stainless steel. One of the problems associated with porous materials is its susceptibility towards wear. To overcome the same, hard biocompatible coatings such as TiN [55], TiAlN [56], AlCrN [57] and DLC [58] materials can be coated on the porous alloys.

6. Conclusions

The biocompatibility of austenite stainless steels has been established over the years. Although release of nickel ions has adverse effects on human body but still stainless steels have got fair and restrained applications in biomedical field. Development in Ni-free stainless steel with high nitrogen content with subsequent annealing of it has shown promising results in mechanical, wear and corrosion properties. HNS is showing promising results

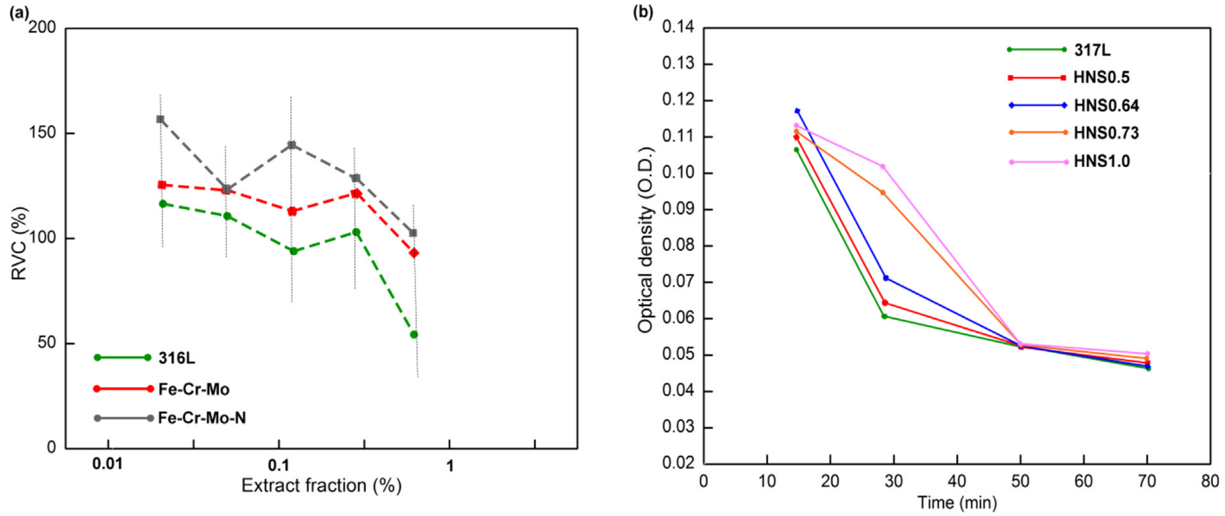

Fig. 5. (a) Cytotoxicity of various HNS [30] and (b) kinetic clotting [31].

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in resistance to crevice corrosion, kinetic clotting and reduced cytotoxicity. The wide gap and mismatch in elastic moduli of stainless steel and surrounding bone can be dealt with increasing the porosity of stainless steel implant which subsequently leads to bone growth and prevent osteogenesis. Also, to further enhance the resistance to wear and corrosion, hard biocompatible hard coatings such as TiN, TiAlN, AlCrN and DLC among others can be applied on the implant's surface.

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