Review of the regulations for the use of stainless steels for orthopedic implants in Argentina

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Abstract. Motivated by the relatively high rate of failure of orthopedic implants in Argentina, the authors review the current normative regulating the use of stainless steels in the fabrication of these metallic parts in the country, and compare it with the regulations currently in use in other countries. The analysis shows that several standards in effect in the country do not comply with broadly recognized international standards. This situation is aggravated by a recent revision of the normative that failed to improve the quality standards to reach levels similar to those applied in developed countries or even in MERCOSUR associates. The national organization in charge of implant certification in Argentina, complying with the law, accepts the applicability of IRAM standards to certify stainless steels implants. In the opinion of the authors, the current practice used to certify implants does not guarantee the structural stability and biocompatibility of the devices, increasing the risk of failure in service, and escalating the cost of the public health care system.

1. Introduction
The use of metals in the fabrication of orthopedic implants started early during the 20th century. In 1926 the first applications used AISI 302 type stainless steel (SS), while the use of AISI 316 SS began around 1940 [1]. The use of metals in implants has been studied extensively over the last 80 years. As a result, the regulations dealing with the use of different metals have evolved continuously, progressively setting more rigorous quality standards, so as to guarantee a better performance in service. In recent years the superiority of Ti based alloys for many implant applications became evident, as these alloys display high strength, low density and excellent corrosion resistance and biocompatibility. Co base alloys have also demonstrated very good properties for implants, but their high density represents a disadvantage. Stainless steels, on the other hand, have progressively lost the preference of implant makers due to their relatively lower potential performance. Nevertheless, stainless steels are noticeably cheaper than Ti and Co alloys, and continue to be used extensively in countries where patients or public health systems cannot afford the high cost of Ti or Co implants, such as Argentina. One frequent cause of failure of SS implants is that a large fraction of the population is allergic to Nickel [1]. The identification of an allergic condition of the patient “a priori” is difficult. An additional fact that prevents the use of SS is the relatively large number of failures in service reported in the past. Nevertheless, many of these failures took place on implants that were produced using SS grades that are no longer accepted. Furthermore, there are numerous reports of successful application of SS in the fabrication of implants that remained in service over extended
periods of time, without showing signs of degradation or rejection. In addition, a number of studies on the use of SS for implants allowed recognizing chemical and microstructural characteristics that are detrimental to the performance of this material. As a result, the specific standards for implant applications were progressively modified, and the quality and the expected performance of this material improved markedly.

Unfortunately the normative regulating the use of SS implants in Argentina did not advance in the same manner. At the same time, different sources report high rates of failure and rejection, although precise numbers and causes are not known. In this article, the authors review the international regulation for the use of SS in implants and its evolution, and compare it with the standards currently in use in Argentina.

2. International normative

Taking into account the limited space available in this article, the review will focus on the recent evolution of the more frequently accepted international standards, such as ISO and ASTM, which are also the standards used by IRAM, the materials standardization agency of Argentina, as reference regulations.

The use of SS in implants by 1980 was regulated by standards that can be grouped into two different categories. The first set of standards prescribed the use of a SS commonly known in the industrial practice as AISI 316L. This was done by the standards ASTM F55/82 [2], ASTM F56/82 [3] and ISO 5832-1/87 [4]. The second set of standards described a steel referred to as “special quality SS”, as in standards F138/86 [5] and F139/86 [6]. For the first set of standards, the SS prescribed for implants is in fact almost identical to the industrial SS grade AISI 316L (ASTM 240/94) [7]. The chemical compositions are listed on Table 1. The similarity between the implant material and the industrial SS led to the customary use of the term “AISI 316L”, to refer to the implant grade. In fact, this term is still in use both at the local and the international levels. Nevertheless, as we shall see, the denomination used is currently incorrect, and probably leads to troublesome misunderstandings. The second set of standards included two chemical compositions, only one of those of low carbon content.

Table 1. Chemical compositions of stainless steel alloys in use by the end of the XXth century

| Element (%) | ASTM F55 – F56 | ASTM A-240/94 | IRAM 9401/88 | IRAM 9403/93 |
|-------------|----------------|--------------|--------------|--------------|
| Carbon      | 0.03 max       | 0.03 max     | 0.08 max     | 0.03 max     |
| Silicon     | 1.00 max       | 0.75 max     | 1.00 max     | 1.00 max     |
| Manganese   | 2.00 max       | 2.00 max     | 2.00 max     | 2.00 max     |
| Phosphorus  | 0.045 max      | 0.045 max    | 0.045 max    | 0.045 max    |
| Sulfur      | 0.030 max      | 0.030 max    | 0.030 max    | 0.030 max    |
| Copper      | n/s            | n/s          | n/s          | n/s          |
| Nickel      | 10.0 - 14.0    | 10.0 - 14.0  | 10.0 - 14.0  | 10.0 - 14.0  |
| Chrome      | 16.0 - 18.0    | 16.0 - 18.0  | 16.0 - 18.0  | 16.0 - 18.0  |
| Molybdenum  | 2.0 - 3.0      | 2.0 - 3.0    | 2.0 - 3.0    | 2.0 - 3.0    |
| Nitrogen    | n/s            | 0.10 max     | n/s          | n/s          |

n/s: not specified

The results of many studies demonstrated the advantage of special quality SS for the manufacture of implants, as they are more resistant to the body fluids. As a result, standards ASTM F55/82 and ASTM F56/82 were discontinued in 1991, without a new equivalent. ISO standards followed a similar trend. These changes in the normative implicated the end of the applicability of SS AISI 316L for the fabrication of permanent implants.
Therefore, the use of SS started to be regulated by the standards referring to the formerly called “special quality” SS. These SS include higher contents of alloying elements that confer better corrosion resistance. This category of SS is regulated by ASTM F138/86 [5], ASTM F139/86 [6] and ISO 5832-1/87 [8], and their respective actualizations (ASTM F139/03; ASTM F138/03; ISO 5832-1/97 under revision). The successive actualizations further increased the differences between the industrial AISI 316 SS grade and the special SS for implants. The higher Carbon grade SS was no longer accepted. Table 2 lists the chemical compositions specified by ISO and ASTM for SS used in orthopedic implants nowadays. A Pitting Resistance Equivalent index was included in the standards. This index sets a minimum value for the combined content of Cr and Mo. The accepted ranges of concentration of Cr and Mo were adjusted, and a higher minimum content of Ni was set, aiming to avoid the formation of delta ferrite. As a result, the SS for implants has higher minimum and maximum contents of Cr, Ni and Mo than AISI 316L. At the same time, accepted levels of impurities (S and P) and inclusions are markedly lower in the implant quality SS. Inclusion content limits are listed in Table III. ISO and ASTM standards are identical in this subject.

Implants made from steels satisfying standards ASTM F139/03, ASTM F138/03 and ISO 5832-1/97 have been successfully used in contact with soft tissues and bones for almost two decades [6-7]. Furthermore, the behavior of SS made according to ASTM F138 in contact with the body environment is sufficiently credited to be included as a reference material in standard ASTM F 981/04 [9]. This standard sets the procedures to establish biocompatibility of implant materials.

### Table 2. Chemical compositions prescribed by current standards

| Element (%) | ASTM F138– F139 | ISO 5832-1/97 | IRAM 9401-2/05 | IRAM 9402/06 |
|-------------|-----------------|---------------|----------------|--------------|
| Carbon      | 0.03 max        | 0.03 max      | 0.03 max       | 0.03 max     |
| Silicon     | 0.75 max        | 1.00 max      | 1.00 max       | 0.75 max     |
| Manganese   | 2.00 max        | 2.00 max      | 2.00 max       | 2.00 max     |
| Phosphorus  | 0.025 max       | 0.025 max     | 0.045 max      | 0.025 max    |
| Sulfur      | 0.010 max       | 0.010 max     | 0.030 max      | 0.010 max    |
| Copper      | 0.5 max         | 0.5 max       | n/s            | 0.5 max      |
| Nickel      | 13.0 - 15.0     | 13.0 - 15.0   | 10.0 - 14.0    | 13.0 - 15.0  |
| Chrome      | 17.0 - 19.0     | 17.0 - 19.0   | 16.0 - 18.0    | 17.0 - 19.0  |
| Molybdenum  | 2.25 - 3.0      | 2.25 - 3.50   | 2.0 - 3.0      | 2.25- 3.0    |
| Nitrogen    | 0.10 max        | 0.10 max      | 0.10 max       | 0.10 max     |

n/s: not specified

### 3. Argentinean normative

The Argentinean normative about the use of SS in implants valid by the end of the last century was based on standards IRAM 9401/88 [10], 9402/93 [11] and 9403/93 [12]. These three standards stipulated materials of very different characteristics. IRAM 9402 was based on ASTM F138/86, ASTM F139/86 and ISO 5832-1/87, and stated quality standards similar to those applied in countries of high health care standards at the time of its promulgation. On the other hand, IRAM 9401/88 and IRAM 9403/93 were based on ASTM F55/82 and ASTM F56/82 currently eliminated. Unexpectedly, at the time IRAM 9403/93 was published in 1993, the reference standards ASTM F55 and F56 had already been discontinued from 1991, what indicated that the material was no longer acceptable for permanent orthopedic implants under ASTM standards. The chemical composition of the SS stipulated by IRAM 9401/88 and 9403/93 are listed in Table 1. The compositional limits are very similar to those of the industrial AISI 316L. Standard IRAM 9401 was eliminated later. Nevertheless IRAM 9403 remained valid for more than 20 years and was the base of the certification of a large number of
implants, until it was also eliminated. Its elimination seemed to finish the acceptance of SS AISI 316L for implants in Argentina. Nevertheless, IRAM 9403 was substituted by IRAM 9401-2 [13], where the same requirements of IRAM 9403/93 are essentially maintained. Only the absence of free delta ferrite was included as a mandatory requisite. IRAM 9401-2 reports to have used ISO 5832-1:1997 as a reference, nevertheless, the discrepancies between these documents are noticeable. The reader could assume that IRAM prescribes the use of implants made from materials following IRAM 9401-2 for temporary implants. Nevertheless this does not seem to be the case, since the standard reads “In case this material is used in the fabrication of hip implants, these devices must satisfy fatigue resistance tests prescribed by the applicable standards”. This paragraph clearly indicates that the standard supports the applicability of this material to permanent implants.

The discrepancy between IRAM 9401-2 and ISO 5832-1:1997 is marked. The chemical composition prescribed by IRAM 9401-2 is similar to that of AISI 316L SS. It does not set specific limits for pitting resistance. Nevertheless, if the pitting resistance equivalent is calculated by taking the limit concentrations of Cr and Mo set by IRAM 9401-2, this index will range from 22.6 to 27.9. The minimum value suggested by ISO is 26, what indicates that a significant proportion of alloys that satisfy IRAM 9401-2 will not guarantee pitting resistance. The inclusionary levels required by IRAM 9401-2 are listed in Table III. Again, the differences are marked, as IRAM allows a higher content of inclusions of all types. It is worth to mention that inclusions are known to affect the corrosion resistance of SS, and as a result, to decrease its biocompatibility.

Table 3. Maximum inclusionary levels

| Norma | ASTM F138–F139 | ISO 5832-1/97 | IRAM 9401-2/05 | IRAM 9402/06 |
|-------|-----------------|---------------|----------------|-------------|
| Sulfurs, Aluminates, Silicates, Oxides (globular) | 1.5 | 1.5 | 2.5 | 1.5 |
| Field level | | | | |
| FINE SERIES | | | | |
| Sulfurs, Aluminates, Silicates, Oxides (globular) | 1.0 | 1.0 | 2.0 | 1.0 |
| Field level | | | | |
| COARSE SERIES | | | | |

The situation is quite different for IRAM 9402/06 [14]. This normative sets high quality standards, almost identical to those established by equivalent ASTM and ISO regulations. The chemical composition and inclusionary limits set by IRAM 9402/06 are listed in Tables II and III.

4. Discussion

The analysis of the normative carried out in the previous section shows a marked discrepancy between Argentinean and international regulations. The Argentinean normative shows the coexistence of standards that are similar to international regulations, such as IRAM 9402/06, and standards that are not backed by international regulations, such as IRAM 9401-2/05. Nevertheless, both standards are equally applicable to certify implants under Argentinean regulations.

The differences in the chemical composition and in the level of acceptable inclusions, already described in detail above, may appear to be irrelevant to the reader; nevertheless their influence on the performance of the SS is large and can be critical for the successful application of the material in implants. Low inclusionary levels and carbon content are required to guarantee biocompatibility, pitting resistance, and resistance to intergranular corrosion. Standards for high quality SS for implant applications also set microstructural requirements, such as freedom from delta ferrite and chi and sigma phases. Additionally, maximum grain size and minimum mechanical properties are also
established for strips, sheets and strings. The intermetallic compounds chi and sigma, rich in Mo, must be avoided since they reduce the corrosion resistance and can cause embrittlement. Delta ferrite must be avoided since it is a magnetic phase, and it will impede to perform magnetic resonance tests on the area. The differences between SS AISI 316L and SS fabricated according to ASTM F139 are not only substantial to their performance in service, but also involve significant differences in the manufacture and processing procedures. In order to reach such low levels of P and S and to obtain sufficiently low inclusionary levels, special raw materials and manufacturing techniques must be used, which lead to higher implant cost. In addition, fulfilling the stringent microstructural specifications demands a careful balance of alloying elements and heat treatments. Furthermore, in order to certify the quality of the implants, they must pass other specific tests. Then, it becomes evident that the difference between industrial AISI 316L SS and the modern implant grades cannot be ignored by the experts. Sustaining the acceptability of AISI 316L to manufacture implants in Argentina cannot be accidental, but must be the result of a rational approach. Such approach could have been based on the lack of high quality SS made in Argentina, and the consequent need to use foreign supplies in case locally made materials are not accepted. In authors’ opinion, if the reasons were such, it should have been established that, beyond any reasonable doubt, the improvements in the quality of SS demanded by ASTM and ISO standards, are not necessary to guarantee the correct performance of the material in service. This has not been done, to the best of our knowledge. Furthermore, most of the SS AISI 316L available in the local market is imported.

It is also relevant to compare Argentinean standards to those in effect in countries of the same region and with similar sanitary systems and industrial development. For example, the regulations in Brazil are similar to those set by ASTM F139, ASTM F138 and ISO 5832-1 [15]. The standard NBR ISO 5832-1-97 is almost identical to ISO 5832-1/97, and it is used by the National Agency for Sanitary Vigilance of Brazil as a reference standard for the certification of orthopedic implants made of SS. The Argentinean agency in charge of certification follows a different procedure to validate implants, which is based in the nation’s legislation (Law N° 16.463). The implant material is not required to satisfy a specific standard, but the manufacturer can choose to follow a standard included into a broad universe of internationally recognized standards. IRAM standards are regarded as applicable in this respect. In consequence, SS implant certification can be based on IRAM 9401-2. As this standard involves the use of a more inexpensive material than that required by internationally recognized regulations, it is reasonable to expect that most manufacturers will make use of SS AISI 316L. As a result, many implants manufactured in the country using SS do not satisfy international standards.

Since the authors of this study are not medical doctors, the assessment of the influence of this regulation on the public health in Argentina is not within their reach, nor can they assure that the apparently high rate of failure of SS implants is the result of the current regulations on the use of SS. Careful systematic studies would be necessary. Nevertheless, as trained metallurgists, it is surprising to find that the local standards set quality levels below those applied in USA and Europe, particularly when it is clear that the technologies necessary to obtain SS of low inclusionary levels are well known, and that the production of such materials in the country is possible. Additionally, it must be pointed out that there are several foreign producers of high quality SS fabricated according to ASTM and ISO implant standards that market their products internationally.

After the detailed analysis of the differences between implant grade SS and AISI 316L SS made above, it becomes important to comment about the way in which the high quality grade SS is many times referred to as. Both at the national and the international levels, it is quite frequent to listen to health professionals and other individuals involved in the sanitary systems, to refer to implant quality SS as “AISI 316L”. This is clearly mistaken. The use of such terminology should be avoided since it is not only erroneous but can also lead to improper use of metals for implants.

5. Conclusions
The analysis made shows that while some Argentinean standards regulating the use of stainless steels for orthopedic implants are similar to those applied internationally, other Argentinean standards that can be equally used to certify an implant, deviate significantly from international standards. This inconsistency is aggravated by a recent revision of the Argentinean normative that did not improve the quality levels demanded on stainless steels. As a result, the quality of many implants made in Argentina cannot satisfy quality standards in effect in Europe, USA and also neighbouring countries such as Brazil. The authors believe that the practice currently applied in Argentina does not guarantee the stability and biocompatibility of orthopaedic implants, increasing the risk for the patients and the potential costs for the health care system.

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