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Review

Selected cases of failure analysis and the regulatory agencies in Brazil. Part 1: Aviation, railway and health

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A B S T R A C T

Three cases of failure analysis (aircraft landing gear, cast railway wheel and unalloyed Ti orthopaedic implant) representing three different industry sectors were selected to compose a critical study of their respective regulatory agency in Brazil. The implementation and achieved transparency of the National Civil Aviation Agency (ANAC) for the investigation of aircraft accidents are recognized as state of the art and is consistent with the economic importance of this sector for the country. In contrast, the transparency of the National Land Transportation Agency (ANTT) for the investigation of railway accidents is considered to be deficient. The current organization and transparency of the Brazilian Health Regulatory Agency (ANVISA) for the investigation and prevention of the failure of orthopaedic implants can be criticised as severely flawed. This agency should take immediate actions to adopt the compulsory notification and investigation of the failures of orthopaedic implants and implement a more reliable certification procedure of implants to ensure the protection of the Brazilian health care patients. The transparency of information might play an important role in the trade-off between the independence and the political control of the regulatory agencies in Brazil. In this sense, the publication of conducted failure analyses and general access to their reported findings are seen as a valuable driving force to improve the impact the regulatory agencies have on the general welfare of the country.

1. Introduction

Three cases of failure analysis (aircraft landing gear, cast steel railway wheel and unalloyed Ti orthopaedic implant), representing three different industry sectors, were selected to compose a brief study of their respective regulatory agencies in Brazil, especially in terms of transparency of information (investigation of the accidents and their regulatory responses and actions). Failures of engineering components can result in substantial financial losses unrelated to the initial cost of the component, as well as endangering the environment and human life. In most cases, it is possible to identify the root cause of a failure and prevent future occurrences [1]. Therefore, the failure analysis allows improving the safety levels of an industry sector, as long as producers, operators and regulatory agencies discuss the results and recommendations documented in the failure analysis report with the aim to implement corrective measures [1]. Another paper [2] analysed the transparency of the Brazilian Electricity Regulatory Agency (ANEEL) and the Brazil's National Agency of Petroleum, Natural Gas and Biofuels (ANP) in terms of access to the investigation reports of serious accidents and their regulatory actions, and the transparency of these agencies was recognized as poor. In the present paper, selected cases of failure analysis will be used to assess the transparency of the National Civil Aviation Agency (ANAC), the National Land Transportation Agency (ANTT) and the Brazilian Health Regulatory Agency (ANVISA), and analyse how each agency deals with these failures to improve the safety of these sectors. A general assessment of the transparency and effectiveness of these regulatory agencies will be discussed.

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2. Failure analysis of a landing gear and the role of the Brazilian aviation regulatory agency

The main landing gear of a Fokker F-100 aircraft was inspected in 1999, following the routine report of the pilot after touch down. This inspection lead to the failure analysis of the landing gear [3]. The details of this incident are not published on the website of the National Civil Aviation Agency (ANAC), which is responsible for civil aviation regulation and safety oversight in Brazil [5]. The failure analysis report [3] however, outlines the following details. The inner and outer cylinders of the landing gear were fabricated by forging and heat treatment (solution treatment and two-step ageing) using an Al-5.7Zn-2.7 Mg-0.5Mn-0.5Cu alloy (DTD 5104A) [4]. The attachment lug of the outer cylinder broke into three pieces, causing the failure of the landing gear (see Fig. 1-a to c). The chemical composition and mechanical tensile properties of the material were in accordance with the DTD 5104A specification. The metallographic examination of the region close to the fracture nucleation site revealed a partially recrystallized banded microstructure, oriented perpendicular to the free surface of the bore (see Fig. 2-a and b). The microstructure was composed of recrystallized (light bands) and non-recrystallized areas (dark bands). The former showed equiaxed grains of Al (α) phase (average diameter of approximately 10 μm), intense intergranular precipitation (rich in Zn and Mg) and coarse primary precipitates - $(Fe, Mn)_3Al_{12}$ and Mg_2Si phases. The non-recrystallized grains featured a more refined grain size - approximately 1 μm - and intense presence of a fine intragranular precipitation [3].

Localized corrosion was observed along the perimeter line of the inner surface of the bore, adjacent to the steel bush (see white arrows in Fig. 1-b) and a detailed examination revealed preferential corrosion of the recrystallized areas, leading to the formation of corrosion pits with a depth of 1.3 mm (see Fig. 3-a and b). Additionally, the area located ahead of the tip of the corrosion pit featured intergranular corrosion, consuming preferentially the grain boundaries of the recrystallized area (see Fig. 3-c). The corrosion-assisted cracks propagated up to a critical depth of 1.3 mm, followed by unstable crack propagation (see Fig. 3-d), which mainly progressed along the grain boundaries of the recrystallized areas. Garrido et al. [6] studied the corrosion of Al-Zn-Mg alloys and showed that the primary precipitates preferentially suffered the corrosive attack, leading to the formation of corrosion pits. Zhang et al. [7] observed that the corrosion of an Al-6Zn-2Cu-2 Mg alloy took place by the formation of corrosion pits, leading to intergranular corrosion. The authors [7] mentioned that the corrosion pits were preferentially formed at the weak points of the passive film, such as the grain boundaries, indicating the corrosion mechanisms were rather sensitive to the orientation of the microstructure.

Concerning the presence of a partially recrystallized microstructure with second phase brittle particles (see Fig. 2-a and b), Patton et al. [8] stated that 7010 Al alloys (AlZn6MgCu) are especially interesting due to their multiphase nature (partially recrystallized microstructure with brittle second phase particles). Depending on the process characteristics, the size and volume fraction of these two microstructural features can be varied in order to obtain the right balance of mechanical and corrosion properties, for instance. The microfractographic examination showed a great proportion of ductile intergranular fracture (see Fig. 4-a to d) on the fracture surfaces, confirming the preferential crack propagation along the grain boundaries of the recrystallized areas (see Fig. 3-d) [3]. The results of the microfractographic examination confirmed the results of the literature, which indicate that the fracture of the Al-Zn-Mg-X alloys is typically by ductile intergranular fracture [8–19].

Pit corrosion, intergranular corrosion and the unstable crack propagation (see Fig. 1-b, a to d) were favoured by the orientation of the microstructure of the forged part, which was perpendicular to the free surface of the bore (see Fig. 2-a and b) [3]. The value of the fracture toughness of the DTD 5104A along the orientation of the microstructure was obtained experimentally (K_{IC} = 13.2 $MPa.m^{-1/2}$) [19]. The effect of the presence of a 1.3 mm deep crack on the fracture stress was quantified using linear elastic fracture mechanics (LEFM), considering mode I loading and using the value of the effective crack depth, which takes into account the internal diameter of the bore. The calculated value of the fracture stress was equal to 38 MPa, indicating that the landing gear fractured due to the presence of corrosion pre-cracks in a brittle material. Additionally, banded microstructures oriented perpendicular to the surfaces [3,19] should be avoided in the design of such critical structural components.

Another failure analysis of the left landing gear of a Fokker 100 aircraft was carried out [19] after an accident without victims during the landing procedure at Santos Dumont Airport, Rio de Janeiro on November 19, 1999. The information now available on the website of the National Civil Aviation Agency (ANAC) [4] states: “The aircraft was flying from São Paulo to Rio de Janeiro carrying 6 crew members and 100 passengers. When heading to runway L20 at the Santos Dumont Airport, the aircraft touched with its main landing gears on the ramp just before the runway, fracturing the left landing gear. As a result, the aircraft slightly went up and, at the second touch on the runway, the left landing gear broke off, followed by the touch of the aircraft's left wing on the ground and the deviation of the aircraft to the left side of the runway, stopping on the grass. The evacuation of the passengers happened through the front door without problems, leaving all the passengers and crewmembers unharmed. The aircraft, however, suffered serious damage.” The published investigation [19] confirmed that the macroscopic fracture of the left landing gear was found to be brittle, which was associated to the presence of a fatigue crack with a critical depth of 0.6 mm. The value of fracture toughness of the DTD 5104A perpendicular to the orientation of the microstructure was obtained experimentally (K_{IC} = 21.3 $MPa.m^{-1/2}$) [19]. The calculated value of the fracture stress was equal to 144 MPa, suggesting that the landing gear fractured due to mechanical overload at touch down.

3. Brief study of the national civil aviation agency

Brazil is the third largest domestic aviation market in the world and has six of the ten busiest airports in Latin America. At the same time, Brazil is one of the five countries in the world that manufacture commercial aircrafts. In this sense, the country has an established aerospace manufacturing sector and produces a wide range of aerospace products. Best known for producing regional jets, Brazilian manufacturers also supply turboprops, military aircrafts, agricultural aircrafts and helicopters [20]. Hence, it is not

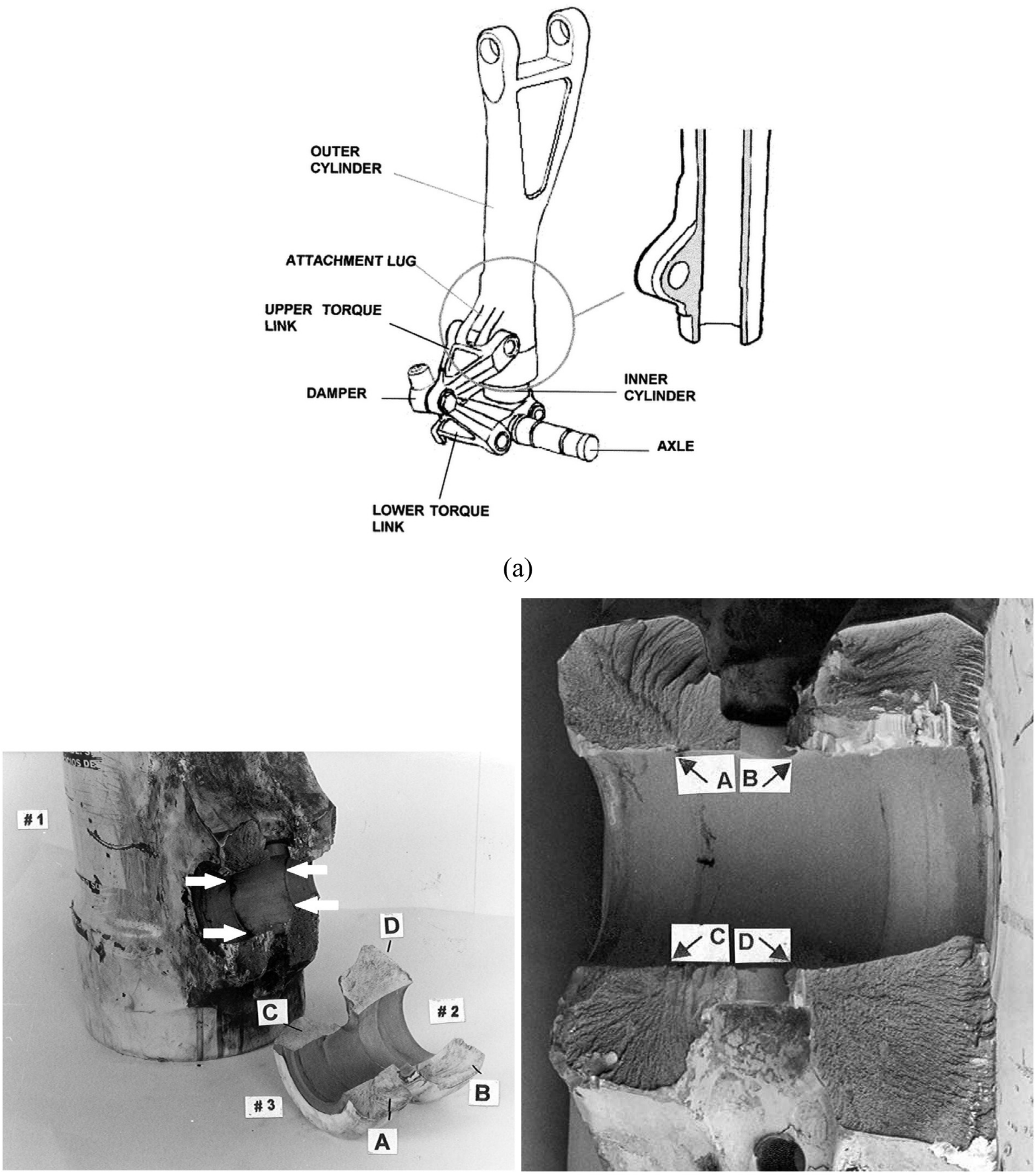
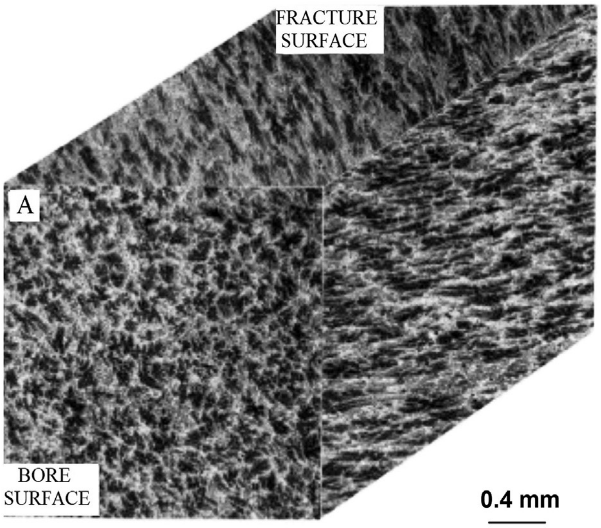


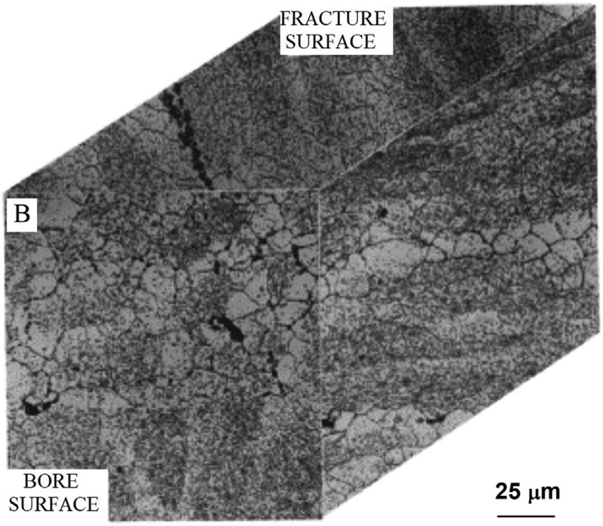
Fig. 1. (a) Scheme of the aircraft's landing gear. Detail shows the location of the attachment lug [3]; (b) Attachment lug of the outer cylinder broke in 3 pieces (#1, #2 and #3). Arrows point at the corroded lines found along the perimeter of the bore, coinciding with the end position of the steel bushes assembled by interference; (c) General view of the fracture surfaces, mostly showing radial marks pointing to the origins of the fracture: the corroded lines found on the bore surface (see white arrows in Fig. 1-b) [3].

surprising that the standards of the audits of the International Civil Aviation Organizations (ICAO) of Brazil are well above the worldwide average and close to developed countries, such as Germany and the USA, in terms of legislation, organization and accident investigations, see Fig. 5 [21-22].

The National Civil Aviation Agency (ANAC) was established in 2005, incorporating the staff, structure and responsibilities of the



(a)



(b)

Fig. 2. (a) and (b) Three-dimensional microstructure of the outer cylinder attachment lug, showing the planes parallel to the bore and fracture surfaces (near arrow A, Fig. 1-c). The light bands of the oriented microstructure are composed of recrystallized grains (~ 10 μm), primary (Fe, Mn)$_3$Al$_{12}$ and Mg_2Si precipitates and intergranular Zn-Mg-rich precipitates, while the dark bands are composed of non-recrystallized grains (~2 μm) and intragranular precipitation. Optical microscopy. Etching: 10% H_3PO_4 at 60 °C [3].

former civil aviation authority, the Department of Civil Aviation (DAC). ANAC is now responsible for civil aviation regulation and safety oversight in Brazil. The President of Brazil nominates the five civilian directors of this regulatory agency for a five years term and their nominations must be approved by the Infrastructure Commission of the Brazilian Senate. ANAC is a special federal autarchy with the status of a regulatory agency, which is linked to the Ministry of Transport, Ports and Civil Aviation, with an annual budget of approximately USD 200 million and 1700 employees. Along with ANAC, the following organizations are part of the Brazilian Civil Aviation System: the Centre for the Investigation and Prevention of Aeronautical Accidents of the Brazilian Air Force (CENIPA); the Department of Airspace Control of the Brazilian Air Force (DECEA); the Brazilian Airport Infrastructure Enterprise (INFRAERO); and the Civil Aviation Secretary (SAC) [5]. The main responsibilities of ANAC involve: the inspection of civil aviation aircrafts, their components, equipment and maintenance services, aiming at ensuring compliance with the flight safety rules; the establishment of flight safety, performance and efficiency standards; the participation in the Brazilian System for the Investigation and Prevention of Aeronautical Accidents (SIPAER) and the collaboration with the Centre for the Investigation and Prevention of Aeronautical

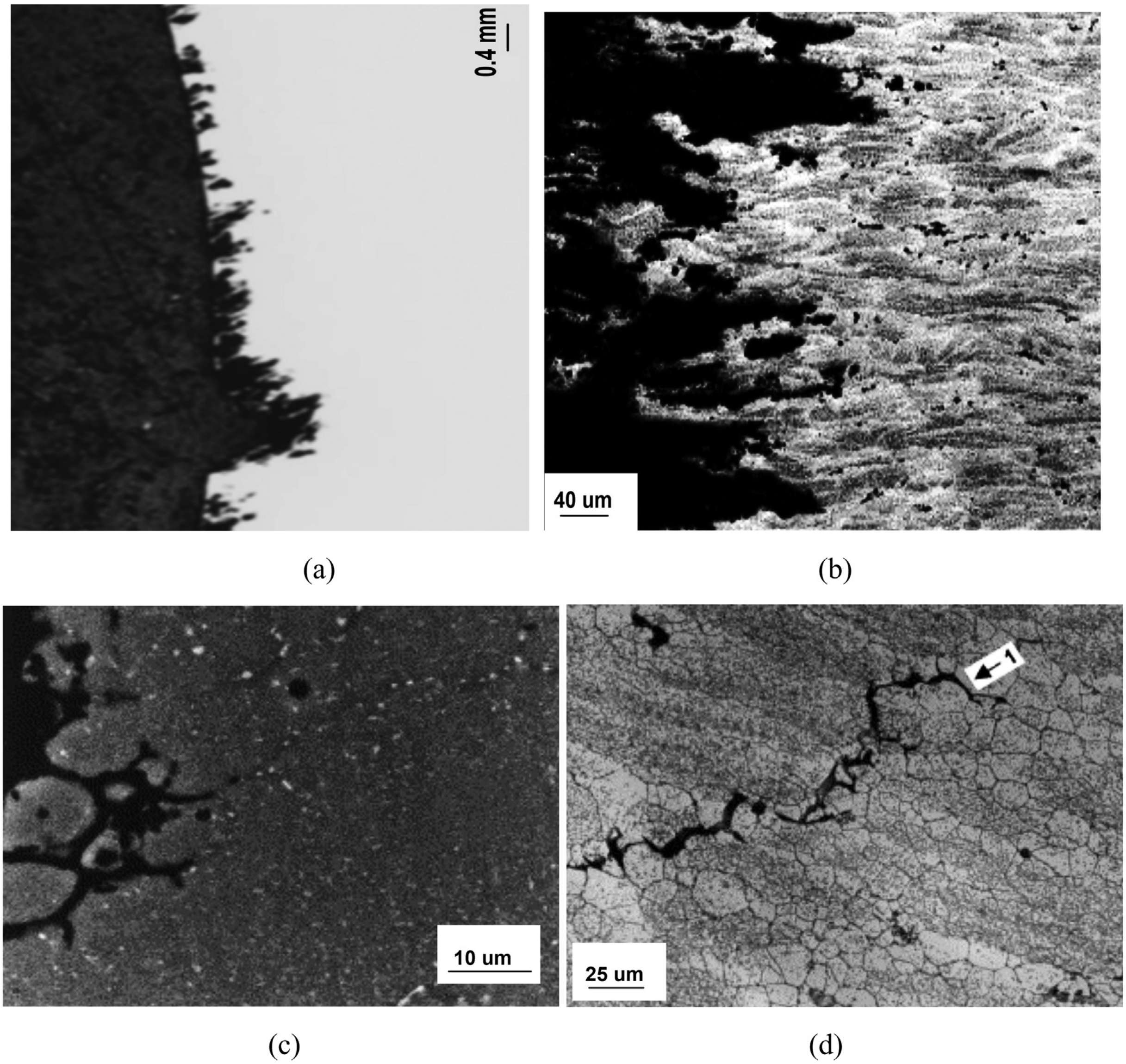


Fig. 3. Examination of the corrosion line along the perimeter of the attachment bore (see white arrows in Fig. 1-b). (a) Presence of pit cavities along the perimeter line of the attachment bore. Optical microscopy [3]; (b) Pitting corrosion following the orientation of the microstructure and consuming preferentially the recrystallized areas. Optical microscopy. Etching: Keller's [3]; (c) Detail of the intergranular corrosion in the recrystallized areas ahead of the pitting corrosion tip. SEM-BEI [3]; (d) Propagation path of a secondary crack along the grain boundaries (see arrow 1). Optical microscopy. Etching: Keller's; (see arrow 1).

Accidents of the Brazilian Air Force (CENIPA).

In terms of the transparency of information related to the aeronautical accidents, the ANAC's website lists the accidents of aircrafts in Brazil between 2007 and 2013, allowing public access to their respective investigation reports [23]. Additionally, the CENIPA [24] allows public access to the investigation reports of the accidents of aircrafts in Brazil between 2008 and 2018 [25]. As a result, the official reports of the investigated failures of the landing gears [3,19], which took place in 1999, cannot be accessed. Compared to the previous military agency, the Department of Civil Aviation (DAC) - which existed from 1931 to 2006 - ANAC has provided a better transparency with regard to the investigation of the aeronautical accidents in the country.

4. Failure analysis of a railway wheel and the role of the Brazilian railway regulatory agency

A train derailed on June 2, 2003 and 46 of the wagons flipped over [26,27]. According to available information, the train loaded with iron ore had travelled along the route between Carajás in Pará and the Port of Ponta Madeira in São Luiz do Maranhão (the total length of this line is equal to 892 km). This is the main route for the export of iron ore from the Amazon region. Brazil is the second

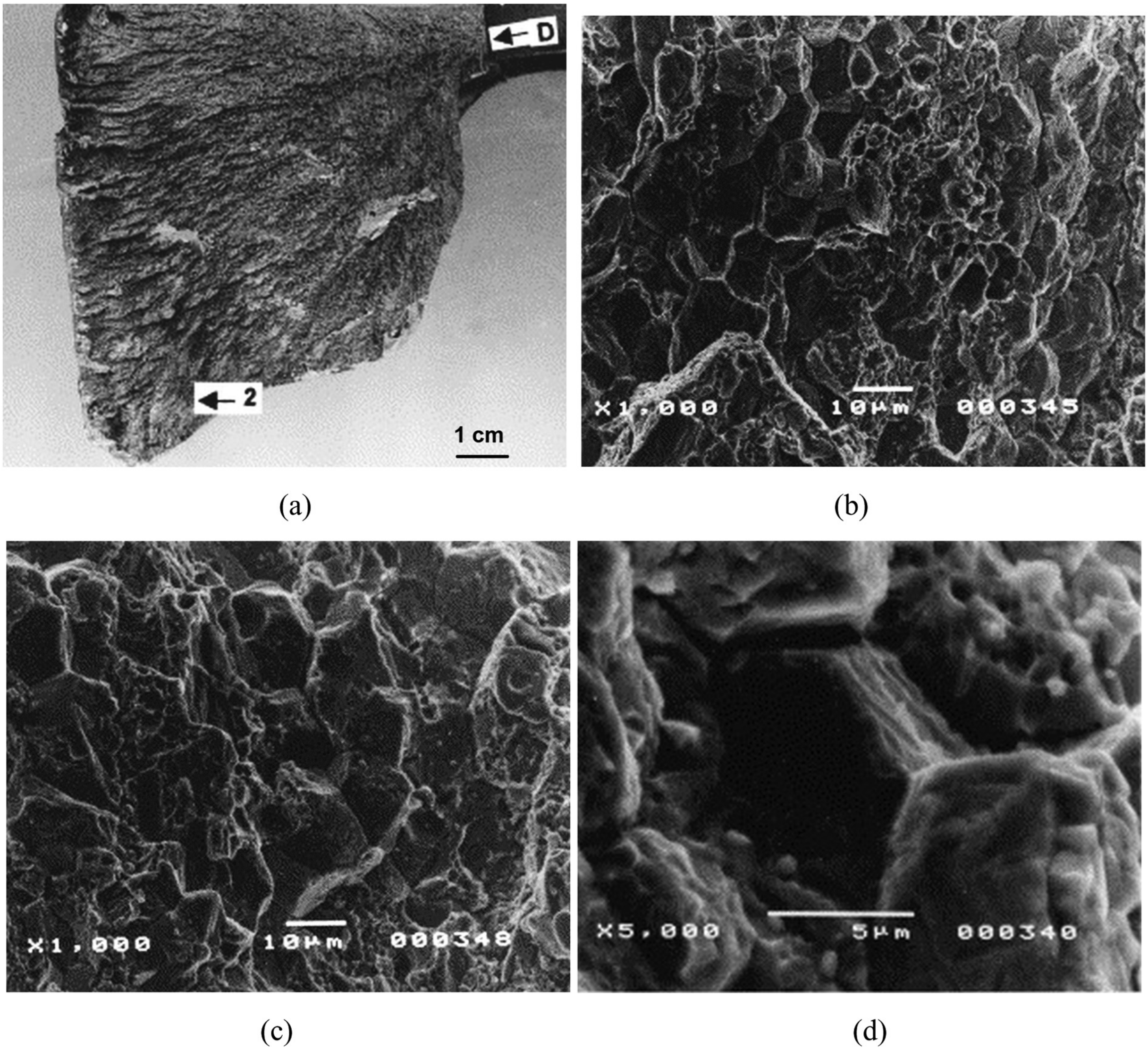


Fig. 4. (a) Fracture surface of lower-right sector of the lug, sector D (see piece 2, in Fig. 1-b), radial marks pointing to the origin of the fracture (see arrow D); (b) Intergranular fracture near the crack nucleation site (arrow D); (c) Intergranular fracture (arrow 2); (d) Typical intergranular cracking showing ductile intergranular fracture. SEM-SEI [3].

largest iron ore producer and exporter in the world (390 million tons per year in 2011, with 85% for export) while 30% of the total volume is explored within the state of Pará in the Amazon region. China purchases approximately 50% of Brazil's iron ore [28]. However, an account of this serious accident and its environmental consequences (possible spilling of ~5000 tons of iron ore) is neither made available within the report of the National Land Transport Agency [29] nor on the worldwide web.

The article by Fuoco et al. [26] investigated the fracture mechanism of a single cast steel railway wheel, which, according to the railroad concessionaire, caused the train derailment (see Fig. 6-a). The visual inspection of the fractured wheel in the as-received condition (after sampling by the other investigators) did not show evidence of beach marks, which are usually observed on fatigue fracture surfaces (see Fig. 6-b). Fig. 6-b showed the presence of chevron marks, typical of brittle fracture. Note that there are two different orientations on the fracture surface, suggesting that the fracture of the wheel occurred due to two subsequent loads (two-stage fracture, see Fig. 6-c). In the first step, the crack propagated from the plate to the tread region of the wheel. In the final stage, the fracture of the wheel took place in the tread region, almost at 90° of the initial orientation. Apparently, the first mechanical load promoted an unstable crack growth in the plate region, which propagated along the hub area in the direction of the tread, where it found a thicker section, which caused its arrest. As a new mechanical load occurred, the final rupture of the tread took place. As the new crack propagation starts (stage 2), it features initially a flat surface before the formation of new chevron marks (see Fig. 6-b). Fig. 6-d shows a typical microfractography found in the fractured cast steel rail wheel with pearlitic microstructure. The fracture surface consists of transgranular cleavage, without any evidence of the presence of fatigue striation marks or any intense secondary

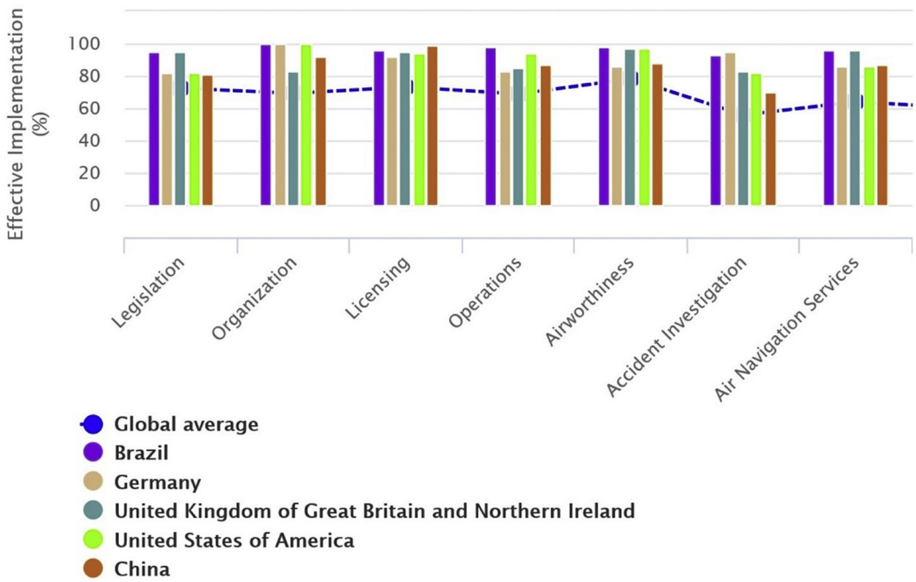


Fig. 5. International Civil Aviation Organization's Universal Safety Oversight Audit Programme. 'Effective implementation' score for the seven categories (such as accident investigation), comparing Brazil with Germany, UK, USA and the global average (dotted lines) [22].

cracking at the interface between the ferrite and cementite phases of the pearlitic microstructure [26].

The microfractographic features of this wheel (see Fig. 6-d) were compared to standard fatigue and overload rupture samples, which were extracted from this very same wheel and submitted to fracture toughness and fatigue crack propagation (da/dN versus ΔK) tests [27,30]. Fig. 7-a and b show the microfractographic characteristics of the stable and unstable crack propagation regions of the fracture toughness (K_{IC}) specimens extracted from the wheel. The region of stable fatigue crack propagation (see Fig. 7-a) show the "typical" fatigue striation marks of pearlitic steels [26,31–33], with some regions displaying intense secondary cracking along the interface between the cementite and ferrite phases. The microfractographic examination of the region of unstable crack propagations revealed a typical aspect of transgranular cleavage of pearlitic microstructures, which is comparatively smoother and more faceted, without secondary cracking along the interfaces between the ferrite and cementite phases (see Fig. 7-b) [26].

One of the reports commissioned by the concessionaire [30] showed a microfractography containing "cleavage facets" in middle of the region of stable propagation of the sample after the (da/dN versus ΔK) crack propagation test (see Fig. 8). The other report [27] stated that the presence of cleavage facets on the fracture surface of pearlitic microstructures not only characterizes the region of unstable fracture, but they can also be observed in the regions of the stable fatigue crack outside the Paris-Erdogan regime. However, one can observe in this microfractography the presence of regions with a rougher surface, usually associated with the intense interlamelar cracking along the interfaces between the ferrite and cementite phases of the pearlite, which are typical features of the fatigue fracture (see Fig. 7-a) observed in pearlitic microstructures [31–33].

In fact, the microfractography of pearlitic steels after fatigue fracture shows a large diversity of topographies for each pearlitic colony, depending on the orientation of the lamellar eutectoid in relation to the cyclic shear stress [31–33]. The stable propagation of a fatigue crack can be parallel or perpendicular to the carbide orientation of the pearlitic colony. A characteristic microfractographic feature of the fatigue fracture in perlite microstructures is the presence of intense secondary cracking along the interface between the ferrite and cementite phases in some pearlitic colonies. El-Shabasy et al. [31] studied the effect of the loading coefficient (R) and the testing temperature on the fatigue fracture surfaces of a eutectoid steel and determined the (da/dN versus ΔK) crack propagation curves. They showed that there is a significant proportion of fatigue striation in the regions of stable crack propagation within the Paris-Erdogan law regime and this proportion is gradually reduced with an increase of ΔK. Toribio et al. [32] investigated the fatigue fracture of pearlitic steel bars, showing fracture surfaces with intense secondary cracking along the interfaces between ferrite and cementite. The stable propagation of fatigue crack along the pearlitic colonies was not uniform, but subject to deflections, bifurcations and secondary cracking, producing a variety of microfractographies, depending on the values of the R coefficient and ΔK. The authors, however, did not show any regions of the fracture featuring transgranular cleavage (see Fig. 9-a and b).

The microfractographic examination of the fractured wheel did not produce any evidence of the action of a fatigue mechanism, indicating that the investigated wheel failed due to mechanical overload, probably because of the train derailment [26]. Nevertheless, the reports commissioned by the concessionaire [27,30] claimed that the derailment of the train was caused by the fatigue fracture of the wheel, which was nucleated at shrinkage porosities of approximately 300 μm of length. Only a single wheel of the train composition (chosen by the concessionaire) was investigated in order to explain the derailment to the regulatory agency. The mere interpretation of microfractographies of pearlitic microstructures can create dissimilar narratives to explain the failure mechanisms and, consequently, interfere in the solution of commercial conflicts.

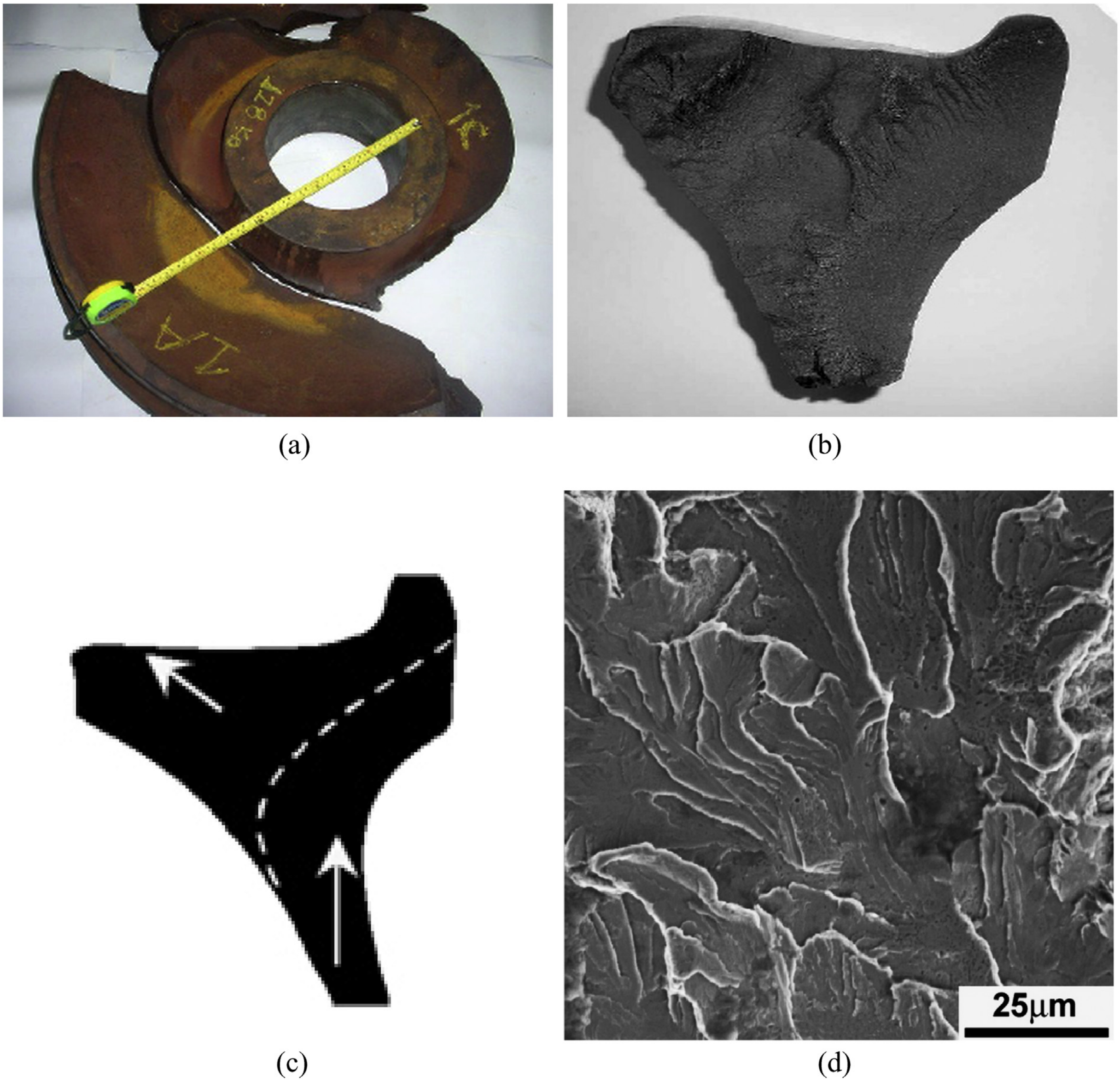
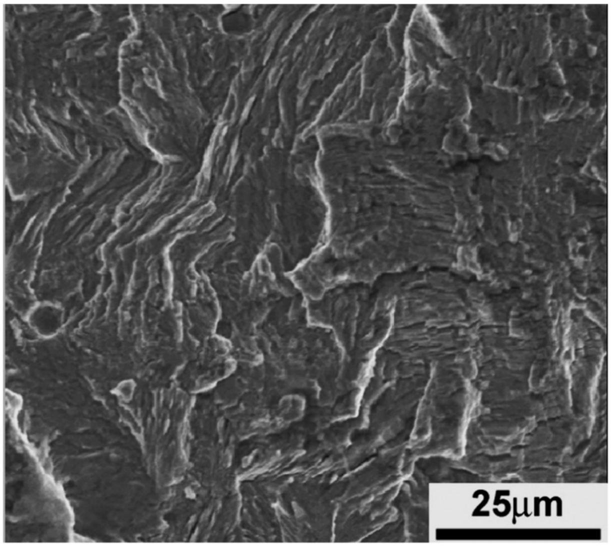


Fig. 6. (a) General view of the broken wheel; (b) General view of the main fracture surface between the plate and the tread regions of the wheel; (c) Scheme illustrating the crack propagation between the plate and the tread regions of the wheel (see Fig. 6-b); (d) Typical microfractography found on the broken pearlitic cast steel railway wheel, showing transgranular cleavage fracture. SEM, SEI [26].

5. Brief study of the national land transportation agency

In the 1920's, the Brazilian railway network was 26,000 km long. In the 1990's, its length had only increased to 29,000 km, just before the privatization program promoted by the government to improve the quality and the extension of this strategic infrastructure component. Following the reforms of the concession system, the freight transport tonnage increased from 38.7 million ton-kilometres in 1996 to 46.3 million ton-kilometres in 1999, but the length of the Brazilian railway network has not increased. Actually, 33% of the network are currently considered as out-of-order. Furthermore, the railway network carries only 21% of the total freight in Brazil (half of the desirable international average) and heavy investments in the order of USD 80 billion are needed to improve the overall railway infrastructure [34–36].

The National Land Transportation Agency, ANTT, is an autarchy of the Brazilian government, linked to the Ministry of Transport, Ports and Civil Aviation, with an annual budget of approximately USD 100 million and 1300 employees. The agency was created in June 2001 and its goal is to "ensure to users the adequate provision of services of land transport and the operation of highway and railway infrastructure". The agency regulates and establishes the conditions so that land transportation services are provided with an acceptable level of efficiency, safety, comfort and punctuality. The agency is also responsible for all the regulations concerning the



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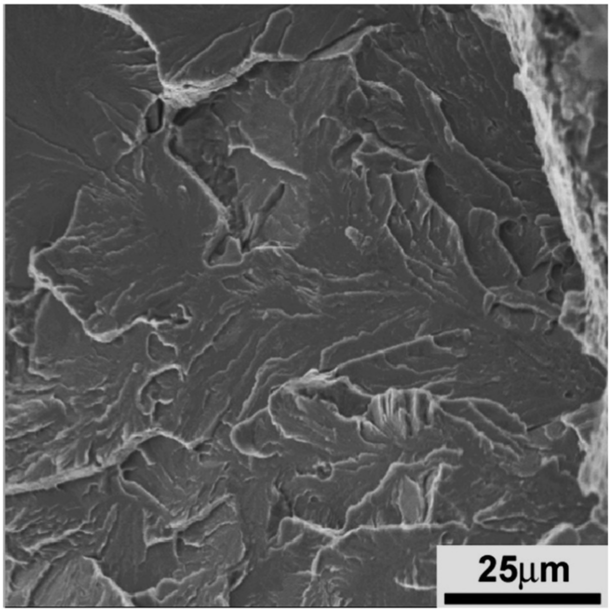


(b)

Fig. 7. Microfractographic examination of the fracture toughness sample after mechanical testing. Broken as-cast railway wheel with a pearlitic microstructure (a) Region of stable crack propagation, exhibiting atypical fatigue striations in different orientations and secondary cracking along the interface between ferrite and cementite (pearlitic colonies). The fatigue propagation mode does not exhibit the classical striations, which are usually observed in pure metals and ductile alloys; (b) Region of unstable crack propagation (overload), exhibiting transgranular cleavage fracture. SEM, SEI [26].

concession of railways in Brazil. In 2002, ANTT issued a resolution (ANTT n° 44/2002), instituting the procedures for the concessionaries to report serious railway accidents in Brazil [37]. This resolution created a performance monitoring system of the railway concessionaries (SIADE), which promoted the creation of an online system for the registration and monitoring of rail accidents (SAFF). With the operation of this system, the "concessionaries could supply detailed information" about the railway accidents; however, none of the collected data is made available for public access [38–40]. In 2006, a resolution [41] was released (ANTT n°1431/2006), establishing the requirements and process to report railway accidents, defining and classifying serious railway accident. Serious accident was defined by the death or serious body injury of a person (causing temporary or permanent incapacity), the interruption of rail traffic, losses greater than USD 400,000, environmental damage and any other impact or damage to the affected population. Moreover, the concessionaires should notify the occurrence of any serious rail accident to the regulatory agency within

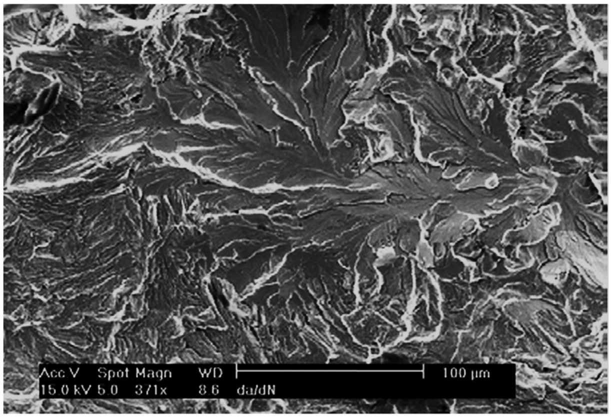
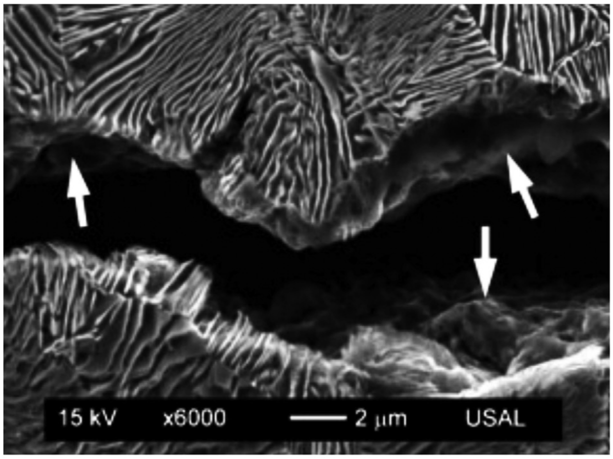


Fig. 8. Microfractographic examination of a da/dN x ΔK sample after mechanical testing, middle of the region of stable crack propagation of the sample. The lower left part of the figure shows atypical fatigue striations in different orientations and secondary cracking along the interface between ferrite and cementite (pearlitic colonies), while the upper centre of the figure exhibits typical transgranular cleavage fracture. SEM, SEI [30].



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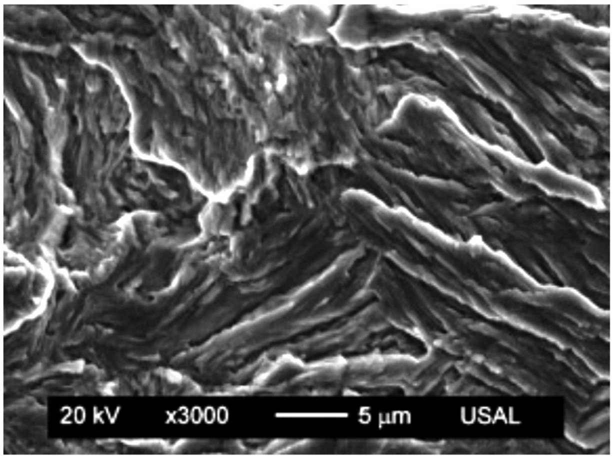


(b)

Fig. 9. Fatigue fracture of pearlitic steels. (a) The fatigue crack propagation the pearlitic steel shows microplastic tearing (see arrows) and secondary cracking along the cementite/ferrite interface. SEM, BEI [32]. (b) The fracture surface of the hot rolled bar (R = 0 and $\Delta K \sim 23\,\mathrm{MPa.m}^{1/2}$) shows intense secondary cracking along the interface between ferrite and cementite (pearlitic colonies). SEM, SEI [32].

Table 1
Railway accidents in Brazil between 2006 and 2013 [29].

Causes	Total	%
Infrastructure, vandalism, signalling, telecommunication and electro technique	65	0.7
Human failure	805	9.2
Rolling material	1283	14.7
Interference of third parties	1283	15.9
Rail track	3315	37.9
Others	1877	21.5
Total	8738	
Total number of deaths (from 2005 to 2018)[a]	849	

[a] Information disclosed by ANTT in October 26th, 2018.

2 h and any serious accident would be subject to an investigation "by the concessionaire", without mentioning the transparency of these reports [41]. In 2011, the agency released another document (ANTT No. 3696/2011), setting the targets for production and the safety of the rail transport in Brazil [42]. The agency would verify the compliance with the set safety targets annually, but the document did not outline the consequences for the concessionaires in case the safety targets were not achieved.

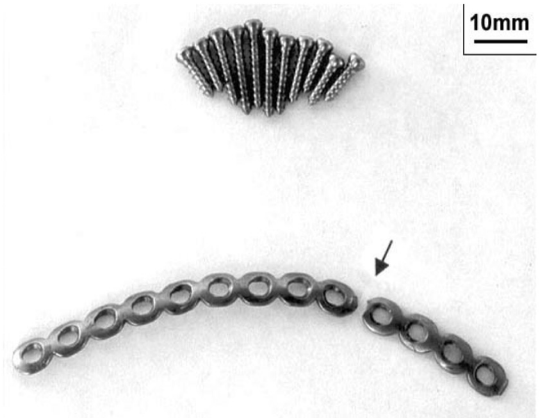
The website of ANTT presents a single document issued in 2014, reporting the statistics of the Brazilian railway accidents between 2006 and 2013 [29], see Table 1. This report indicates that the safety index of the Brazilian railways (number of railway accidents per million train kilometres) decreased from 23 in 2006 to 12 in 2013, and that the total number of accidents decreased from 1638 in 2006 to 866 in 2013. The number of fatalities (passenger, workforce, public and trespassers), potential environmental damage, types of accidents (passenger train derailment or freight trains derailment, collision, level-crossing accidents, etc.) and details of the main serious accidents were not reported in this document [29]. In Europe, for instance in the UK, the rate of accidents was 0.14 (accidents per million train.km) as a four-year average (2010 − 2013) and the worst performing country, Estonia, presented a rate of 3.16 (accidents per million train.km) [43], indicating that the safety of the Brazilian railways is comparatively much lower than the European railways. For instance, Brazil and Australia have a comparably size of railway network (30,000 km) and the National Rail Safety Regulator of Australia (ONRSR) was established in 2012, operating with an annual budget of approximately USD 17.7 million and 49 employees. ONRSR's rail safety report from 2016 to 2017 [44] is much more comprehensive than the ANTT report [29], providing an extensive summary of the rail safety statistics and presenting the details of selected accidents, the methods and model used for the risk-based analysis. Additionally, it produces an analysis of the covered period (data-driven regulatory intelligence, compliance projects, safety improvements projects and major projects) and outlines the national priorities for the next period.

An account of the serious train accident on June 2, 2003 (see Fig. 6-a to d) and its environmental consequences is neither available on the website of the ANTT nor on the worldwide web. According to ANTT guidelines [37–42], the concessionaries have the responsibility to supply all the information about the accident and carry out its investigation. An exhaustive search about train derailments taking place in Brazil during June of 2003 indicated the occurrence of a single serious accident. On June 10, 2003, a train derailed in the state of Minas Gerais and 16 wagons flipped over, spilling 147 tons of granulated potassium chloride and circa of 680,000 l of inflammable liquids (methanol, octanol and isobutanol) on the spring of River Uberaba, causing a serious environmental accident to the city of Uberaba (42,000 m2 of native forest were on fire, and the soil and water were seriously polluted). In January 2003, the safety accident index of this concessionaire was [82].1 (accidents per million train.km), almost 600 times than the UK average safety index. ANTT fined this concessionaire on USD 160,000, while the Brazilian Institute of the Environment and Renewable Natural Resources fined the concessionary on USD 620,000. Moreover, the prosecutors of the city of Uberaba managed to close a deal of USD 4.3 million with the railway company, which was used to environmental recovery and infrastructural investments in the city [45–48].

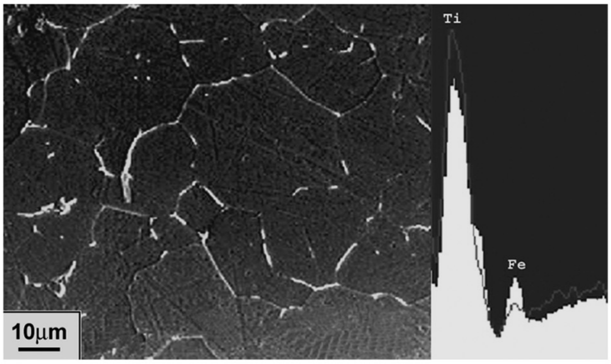
Finally, the failure investigation of railway parts involved in serious train accidents are commissioned by the concessionary, instead of ANTT, which can lead to the communication and documentation of ambiguous information about the accident to the failure analysis teams, impairing its traceability.

6. Failure analysis of metallic orthopaedic implants and the role of the Brazilian health regulatory agency

In 2001 Azevedo and Hippert [49,50] analysed few cases of failure of stainless steel orthopaedic implants (compression and femoral plates) The analysis revealed that the chemical composition of the investigated stainless steel implants was not in accordance with the ISO 5832-1: 2008 standard (Implants for surgery - Metallic materials - Part 1: Wrought stainless steel), especially in relation to the values of the pitting resistance equivalent number (PREN = 3.3% Mo + % Cr), which were below the minimum requirements. Furthermore, the investigated stainless steel implants were missing a manufacturer's name and a product identification, contrary to ISO 6018:1987 (Orthopaedic implants - General requirements for marking, packaging and labelling) and ABNT 15165:2017 (Implants for orthopaedics - Guidelines and requirements for marking, packaging and labelling) standards. One of the positive results of these two publications [49,50] and the following media coverage on television and newspapers was an immediate increase in the sales of surgical grade stainless steel in Brazil (from 50 tons in 2002 to 150 tons in 2004) [51]. The three-fold increase of those sales clearly indicated the previous widespread disregard of some local producers and traders to the most basic standards (chemical composition, marking and labelling) of stainless steel orthopaedic implants.



(a)



(b)

Fig. 10. (a) Overview of the fractured commercially pure titanium plate for osteosynthesis (see arrow pointing at fracture location); (b) Detail of the microstructure of the broken Ti plate, showing equiaxed α grains and intergranular platelets (see left), SEM, BEI. The EDS analysis results (see right) of the matrix (line spectra) and the intergranular precipitates (solid spectra) along with the XRD results suggest that these precipitates are Fe-rich Ti (β) phase [52].

Two further articles of Azevedo et al. [52,53] investigated the fracture of commercially pure titanium plates for osteosynthesis. One of the investigated unalloyed Ti plates (see Fig. 10-a) was provided by the hospital of the University of São Paulo after a revision surgery. Not a single piece of relevant information, such as type of bone fracture, x-rays, life of implant, date of operation, hospital, name of physician, date of reoperation and radiographic documentation; was made available for the investigation. The plate (length of 110 mm, width of 7 mm, thickness of 1.5 mm, diameter of the hole of 3.0 mm and inter-hole spacing of 8 mm) exhibited a curved profile, with the concave surface facing the bone. There were 11 fixation Ti-4Al-6V screws (head diameter of 4.0 mm, screw head with hexagon socket of 2.0 mm, thread diameter of 2.7 mm, core diameter of 2.2 mm and pitch of 1.5 mm), 5 with length of 10 mm, 1 with length of 12 mm, 2 with length of 14 mm and 3 with length of 16 mm. The position of each screw in relation of the fracture was not recorded during the reoperation surgery. The bending angles of the ruptured plate were measured in different points and they varied from 1 to 11°, apparently in accordance with the pre-requisite that the bending must not exceed 15° at any point of the plate [52].

The microstructure of the pure titanium plate (see Fig. 10-b) was formed by equiaxed grains of Ti (α) phase, whose grain size was in accordance with the ISO 5832-2:2001 (Implants for surgery - Metallic materials - Part 2: Unalloyed titanium), which specifies that the grain size should not have been larger than the ASTM grain size 5. The microstructure of the plate, however, presented Fe-enriched intergranular precipitates, suggesting the formation of Ti (β) phase along the grain boundaries. The chemical analysis results of Fe, O, N, C and H confirmed that the plate was in accordance with the requirements of grade I pure titanium of the ISO 5832-2:2001 standard. The presence of Fe-enriched intergranular precipitates, however, is not in accordance with the chemical analysis results, indicating the importance of the participation of IPT in an interlaboratory quality assurance program in order to assess the quality of its analytical chemical analysis of Ti and Ti alloys. The presence of intergranular precipitation in the microstructure of commercially pure Ti implants is undesirable in terms of mechanical properties and corrosion resistance [52].

The slip of pure titanium preferentially occurs on the non-compact prismatic planes along the compact directions [53–57]. The use of titanium and its alloys for the manufacture of orthopaedic implants has been growing since the 1950´s because of their excellent ratio between yield strength and density, high biocompatibility, high corrosion resistance and low elastic modulus (20 GPa for new β-Ti alloys, 100 GPa for unalloyed Ti and 200 GPa for austenitic stainless steels). The high resistance of Ti-alloys to corrosion is due to the formation of a dense TiO_2 oxide barrier in the innermost part of the passive layer, while their excellent osseointegration is due to the formation of a more porous oxide barrier in the outermost part of the passive layer [58–61].

The general view of the fracture surface are show in Fig. 11-a and b. The fracture has a V-shaped surface without shear-lips, showing radial lines (see arrow A) and possibly two crack growth fronts. One of the crack origins is shown by arrow B, while the final rupture occurred near the P-P'segment. The other side of the fracture surface, left to P-P'segment, was mechanical damaged and its microfractographic results could not be interpreted. Grade I commercially pure titanium features a reduction of area of approximately 55%, but the visual inspection of the fracture surface did not reveal any signs of gross plastic deformation. The microfractography of the region near the fracture nucleation (see Fig. 11-c) shows many features, such as plain striation marks, parallel fissured striation marks, "furrow" marks and intergranular and transgranular secondary cracking, typical of fatigue fracture in pure titanium. Fig. 11-d shows the microfractography of the region near the P-P´, which presents a rougher surface and few dimples indicating that the central-V region was the last to fracture. Fig. 11-e shows the microfractographic examination of a sample taken from the investigated plate after fatigue testing (air at room temperature), showing parallel-fissured striation marks in different orientations and intergranular cracking [52].

The small number of slip systems in pure polycrystalline titanium promotes the plastic deformation by mechanical twinning and the microfractographic features of the broken CP titanium plate (see Fig. 11-c to e) are, therefore, the result of a complex cooperation and competition between slip and twinning during the fatigue crack propagation [52–57]. For instance, Fig. 12-a to c show the microstructure of CP titanium plates without anodization after corrosion-fatigue test ($\sigma = 150$ MPa, $R = 0$ and frequency of 10 Hz) in serum at 37 °C. The microstructure close to the corrosion-fatigue crack propagation (see Fig. 12-b) shows higher density of mechanical twinning than further away from the fracture surface (see Fig. 12-a), confirming the action of mechanical twinning during fatigue crack propagation [53]. Fig. 13 shows the details of the lateral surface of the Ti plate, near the notch (see Fig. 10-a), revealing the action of an intergranular corrosion mechanism by the body fluids containing ions Na^+, Cl^- and HCO_3^- [62]. The intergranular corrosion preferentially consumed the intergranular precipitates (see Fig. 10-b), encouraging the formation of corrosion pits (~15 μm deep), which acted as preferential sites for the nucleation of the corrosion-fatigue cracks [52].

The presence of cyclic mechanical loading on the broken Ti plate under service conditions was probably promoted by the existence of mechanical instabilities in the bone/screws fixation. These instabilities can be caused, for example, by the inadequate installation of the implant and/or improper bone repair in the regions adjacent to the fixation screws and/or inappropriate mechanical loading by the patient [62,63–]. The concentration of complex mechanical stresses at specific points of the implant associated with the presence of intergranular precipitation and intergranular corrosion on its surfaces promoted the nucleation and stable propagation of two corrosion-fatigue cracks, causing the premature fracture of the implant [51].

7. Brief study of the Brazilian health regulatory agency

The Brazilian Health Regulatory Agency (ANVISA) is an autarchy with an annual budget of approximately USD 280 million and 2,300 employees, linked to the Ministry of Health as part of the Brazilian National Health System. The agency was created in 1999 to act as an independent administrative entity with the purpose to promote "the protection of the health of the population through sanitary control of the production and marketing of products and services subject to sanitary surveillance." Among its attributions, one finds the "planning and execution of programs of quality control and certification of related products" [64–66]. However, the agency does not request the compulsory notification of the failures of orthopaedic implants in Brazil and there is a lack of statistical data about the failure of these implants [1,49,50]. Moreover, the revision surgeries of orthopaedic implants in Brazil do not follow any of the procedures established by ASTM F 561 (Standard Practice for Analysis of Metallic Implants Retrieved) and ISO 12891-1: 2016 (Implants for surgery - Removal and analysis of surgical implants - Part 1: Removal and handling) standards. These standards specify the methodology for the removal and handling of the surgical implants explanted from patients along with the sampling procedure of the peri-implant tissues and adjacent fluids [1,49,50]. The investigation of the retrieved implant and its adjacent implant tissues is crucial for assessing the quality of the implant, its placement procedure and the potential clinical complications associated with the use of the implant [67–73].

The U. S. Food & Drug Administration (FDA) was created in 1906, presenting nowadays an annual budget of USD 5.1 billion and 14,824 employees. In June 1993, the FDA introduced MedWatch, a medical products reporting program to facilitate the reporting of adverse events and product problems that arise from medical device usage. The recall of orthopaedic implants and any subsequent revision surgery is a serious matter that requires the collaborative efforts of manufacturers, insurers, regulatory bodies, hospitals, and orthopaedic surgeons in order to ensure patient safety [75–78]. In the UK, the Medicines & Healthcare products Regulatory Agency (MHRA), formed in 2003 and employing more than 1300 people [79], is the designated competent authority that administers and enforces the law on medical devices. The European Commission (EC) is the legislator for the medical devices vigilance for the European Community, with each member country having its individual regulatory agency [80,81]. Both MHRA and EC have a range of investigatory and enforcement powers to ensure safety and quality by assessing all allegations of non-compliance; monitoring the activity of notified bodies to assess the compliance of manufacturers; and investigating medical devices related to adverse incident reports [79-81].

In 1997, the National Institute of Technology (INT) in Brazil suggested the compulsory certification of the orthopaedic implants to control the quality of the implants commercialized in the country [74]. The Brazilian Association of Technical Standards (ABNT) has implemented a taskforce to translate most of the standards for orthopaedic implants of the International Organization for Standardization (ISO) into Portuguese, but this sole work is not sufficient to improve the quality of orthopaedic implants commercialized in Brazil [1,49,50]. Up to now, the certification of orthopaedic implants by ANVISA might occur without carrying out the basic

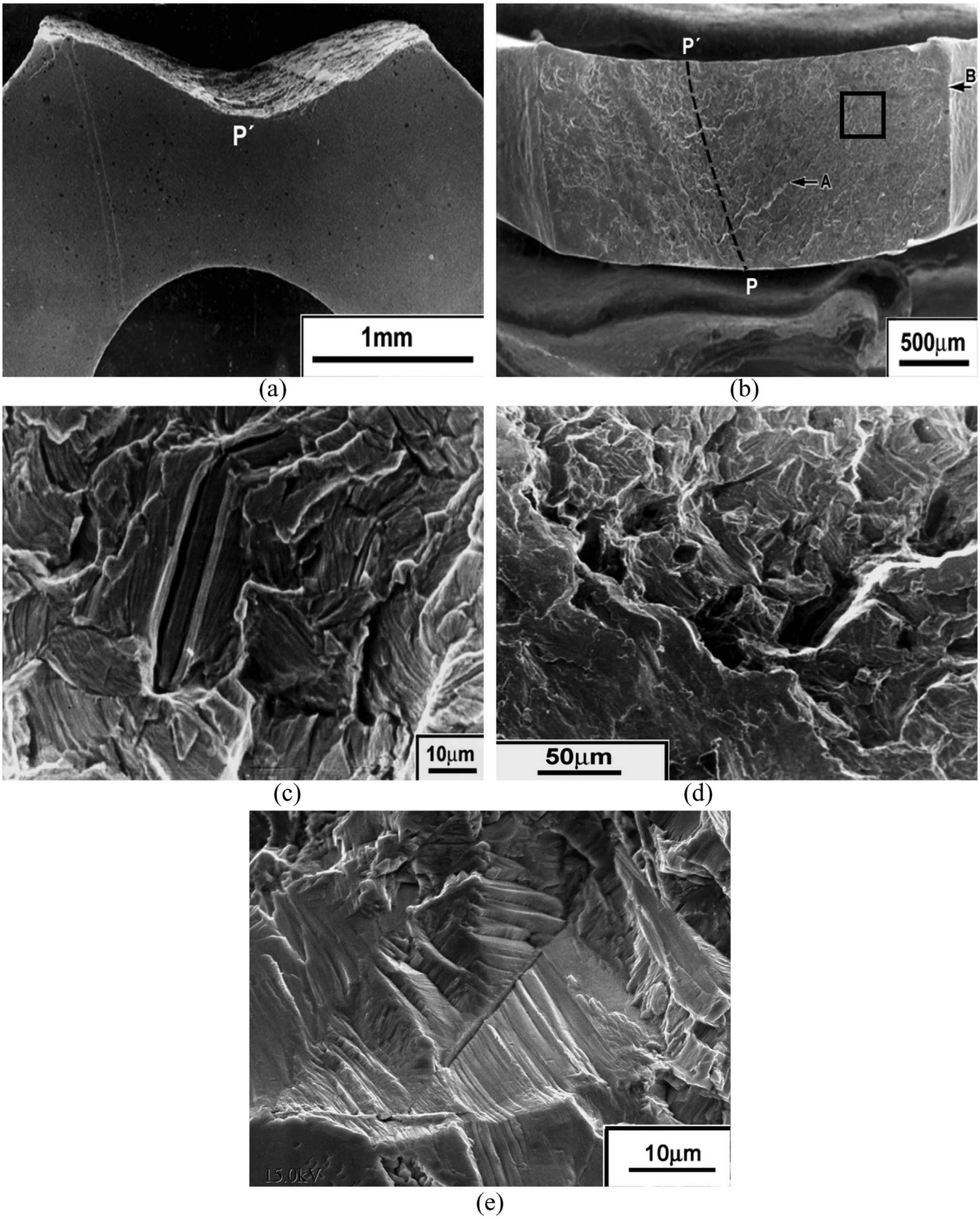


Fig. 11. (a) Detail of the plate near the fracture (bone surface), showing a V-shaped fracture without shear-lips; (b) General view of the fracture surface, showing radial lines (see arrow A) and one of the fracture origins (see arrow B); (c) Microfractographic examination near the fracture origin (see square), showing, parallel-fissured striation marks in different orientations, lentil-like and intergranular cracking [52]; (d) Microfractographic examination near the centre of the fracture (P-P'segment) shows a rougher surface and few dimples [52]; (e) Microfractographic examination of the sample after room temperature air fatigue testing near its fracture origin, showing parallel-fissured striation marks in different orientations and intergranular cracking. SEM, SEI [53].

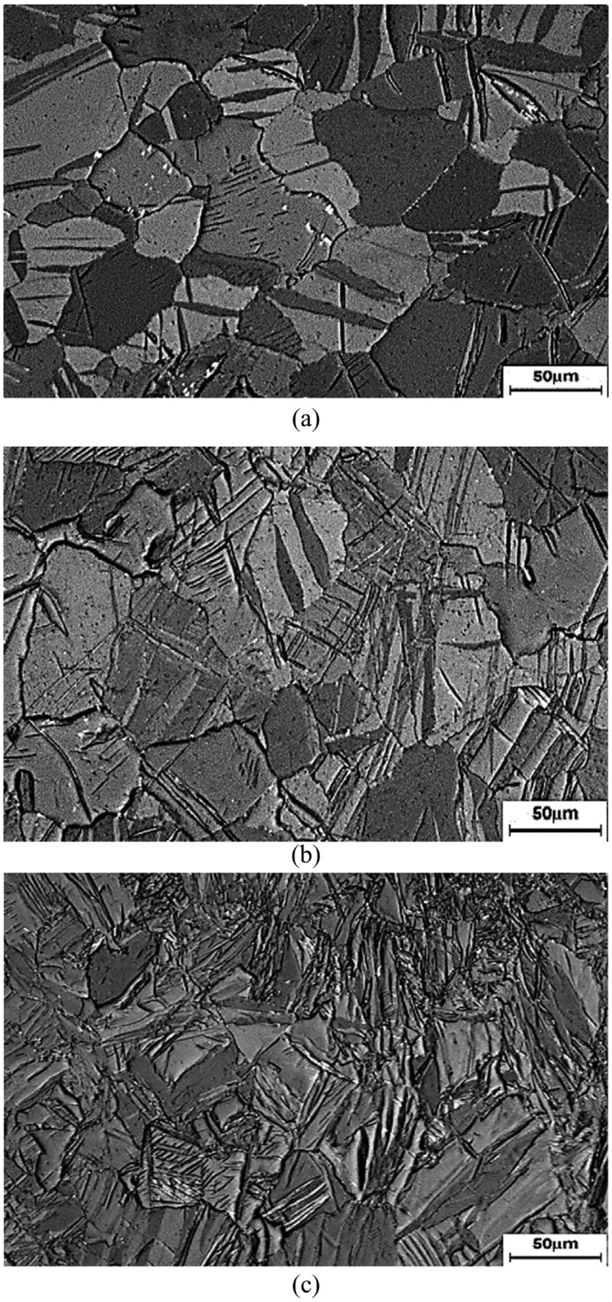


Fig. 12. Microstructural characterization after fatigue testing using non-anodized unalloyed Ti plate in serum at 37 °C. (a) Bulk material away from the fracture, showing equiaxed Ti (α) grains and twinning; (b) Detail near the fatigue fracture origin, showing more intense twinning in the Ti (α) grains; (c) Detail of the overload region, showing a much higher concentration of twinning. Optical microscope. Etching: Kroll, MO [53].

metrological tests of compliance in accordance with the ISO-ABNT standards. The ANVISA's manual for registration of orthopaedic implants, which was published in 2010 [66], cites the word "ABNT" only four times over the 121 pages long document. The compulsory certification of orthopaedic implants used in Brazil based on "metrology" will depend, at some point, on th75] e laboratorial infrastructure of the Brazilian Network of Health Analytical Laboratories (REBLAS-ANVISA), a metrological network created in 1998 by the Secretary of Sanitary Surveillance [82].

The Multicentric Network for the Evaluation of Orthopaedic Implants (REMATO) [83] was created in 2005 by the Ministry of Health to promote actions aimed at the quality and safety of the orthopaedic implants; and foster the adaptation and modernization of the laboratories that will provide services to the qualification of the health industry in the area of orthopaedic implants. In the same year, the government invested USD 3 million into REMATO [84] and a dozen research institutes and universities had their

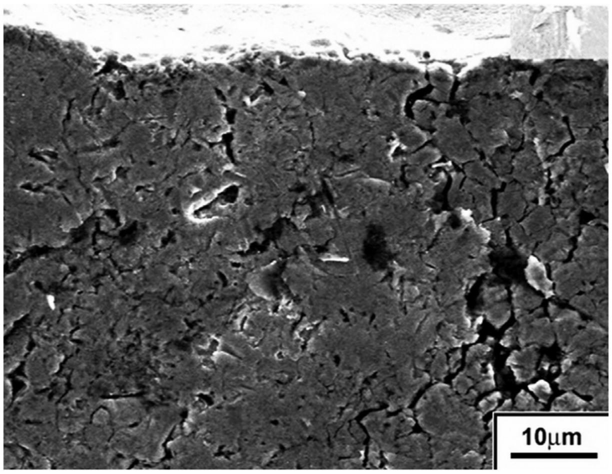


Fig. 13. Detail of the lateral surface of the broken unalloyed Ti-plate. Localized intergranular corrosion and cracking (15 μm deep) on the notch surface of the plate, near the fracture origin. SEM, SEI [52].

projects to improve their laboratorial facilities approved [85], but three of them actually applied for the certification and accreditation in the Brazilian Network of Health Analytical Laboratories (REBLAS-ANVISA). The Biomedical Engineering Group of the Federal University of Rio Grande do Sul, for example, has been accredited since 2009 and has been authorized to perform at least 55 types of mechanical tests on orthopaedic implants [86,87]. In addition, they intensively disseminate their findings related to the failure analysis of orthopaedic implants in specialized journals [88–95]. This illustrates that the investments on the laboratorial infrastructure for the qualification of orthopaedic implants were not able to solve the shortage of accredited laboratories. There seems to be a misbalance between the funding made available and the achieved improvements. There is an urgent need for the regulatory agency (ANVISA) to enforce the basic procedures for the compulsory notification and investigation of the failures of orthopaedic implants and the suitable certification procedure of these implants after systematic metrological characterization in order to ensure the elementary protection of the Brazilian population.

The certification of orthopaedic implants in Europe (CE mark) is delegated to Notified Bodies, which are put in charge to review documentation down to the finest detail of product dossiers including design dossiers, toxicology of implanted material and pre-clinical testing dossiers. They also scrutinize, review and approve protocols for clinical trials designed to gain the CE Mark [80,81,96] as a quality seal. For instance, all medical devices placed on the market in the UK have to comply with two sets of device-specific legislation; the European Union laws (Medical Devices Directives and Regulations) and the UK laws (Medical Devices Regulations). The agency is the designated and competent authority in the UK for assessing whether manufacturers and their medical devices meet the requirements set out in legislation. Manufacturers can apply to any Notified Body in the EU and only once they have the necessary certification, their products can be labelled with the CE mark and sold anywhere in the EU [79-81]. In the USA, owners or operators of places of business that are involved in the production and distribution of orthopaedic implants intended for use in the United States (U.S.) are required to register annually with the U.S. Food & Drugs Administration (FDA) [76–78,97,98].

Brazil's National Health System (SUS), which purchases more than 80% of metallic orthopaedic implants marketed in the country, should promote the use of the available ISO-ABNT standards in the technical description of the orthopaedic implants during the bidding processes [49,50,99], but SUS needs stronger financial and political support to enforce this policy. The National Health System was created in 1988, recognizing health as a right of the citizens and a responsibility of the Government. In 2014, Brazil invested 8.3% of its GDP (USD 144,000 billion) in health, but the Brazilian per-capita health expenditure accumulated only to USD 1109 per person (34th position in the world). The budget of the federal government for health for 2019 is approximately USD 33 billion (USD 180 per capita) [100–104].

In 2013, the National Registry of Implants (NRI) in Brazil was developed by the Federal University of Santa Catarina with support of ANVISA and resources from the United Nations Development Program Project. This system enables the registration of surgical procedures for the implantation of osteoarticular (hip and knee) prostheses and coronary stents performed in the country. The registry will allow matching patients submitted to such procedures with the data from the implanted products and record the professional and health service where the procedures were performed. Among other information, the evolving data will generate a knowledge base on implants, surgical devices and the surgical techniques used allowing to profile and monitor the quality standards of all parts and parties involved in the health service provision. The data can also be useful to adjust the regulation of implantable products, as well as indicating the best therapeutic practices and the most suitable materials. The proposal for a specific regulation for the implementation of the NRI is, however, still under discussion [105].

The present investigation reinforces the imperative need to implement a multidisciplinary investigation procedure of all retrieved orthopaedic metallic implants in Brazil. In a preliminary stage, ANVISA could create a small network of sentinel hospitals working together with accredited research institutes or universities to develop the foundation for a comprehensive diagnosis of implant failures in Brazil.

8. Final comments about the regulatory agencies

The transparency of the regulatory agency can be defined by its procedures, mechanisms, and instruments, which guarantee the disclosure and publication of relevant regulatory and institutional information. In this context, social transparency indicates the involvement of non-institutional actors in the agency's policy-making, including their access to the agency's information, while institutional transparency indicates the transparent management of the agency that is not directly linked to stakeholder involvement [106]. According to the European Commission "Transparency is one of the central pillars of effective regulation, sustaining confidence in the legal environment, making regulations more secure and accessible, less influenced by special interests, and therefore more open to competition, trade and investment" [107].

In terms of the transparency of information related to the investigation of aeronautical accidents, the National Civil Aviation Agency (ANAC) allows public access to the investigation reports and their consequences since its creation in 2005 [23–25]. In terms of legislation, organization and accident investigations the standards of the International Civil Aviation Organizations (ICAO) of Brazil are considered as close to developed countries, such as Germany and the USA [21,22]. Compared to the previous military agency, ANAC has in general improved its contribution to governmental transparency and in particular to the accountability for the investigation of the aeronautical accidents in the country.

The National Land Transportation Agency (ANTT) implemented a performance monitoring system of the railway concessionaries in 2007. This online system is supposed to record all rail accidents in the country. ANTT, however, does not allow public access to the investigation reports and their impact analyses Public access is only given to a single document issued in 2014, reporting the statistics of the Brazilian railway accidents between 2006 and 2013 [29]. Furthermore, ANTT does not provide public access to its regulatory actions to improve the safety of the railways in Brazil, indicating an urgent need to optimize its transparency [38–40]. In fact, ANTT showed the lowest regulatory governance index when compared to other federal regulatory agencies. This index was composed of four sub-indexes assessing, for instance, the autonomy and the accountability of the regulatory agencies. The results indicated that ANTT presents, comparatively, higher autonomy but poor control and accountability. This is seen as contrary to the national trend, where the autonomy and accountability were, on average, more developed than the decision-making process and the regulatory tools. Regulatory governance refers not to the policies that emerge from regulation, but rather to the 'inputs' that go into the regulatory process. In this sense, privatization may generate very little welfare improvement if not combined with robust legal frameworks, appropriate contracts and good regulatory governance, broadly understood as the conditions for the enforcement of laws and contracts by the regulators [108]. The administrative procedures of the regulatory agencies to investigate infractions in the transport sector should follow the principle of transparency as a rule established by the Brazilian Constitution. A recent project of law, authored by Senator J. Serra (former Minister of Planning, Minister of Health, Mayor of São Paulo, Governor of São Paulo state, and Minister of Foreign Affairs of Brazil), increases the upper limit of fines applicable by ANTT to R$ 100 million. According to the Senator, the lack of transparency in the administrative processes of some regulatory agencies has become so unsustainable that "not even" deputies and senators were attended to when requesting information from the regulatory agencies. In this context, according to the Senator, the regulatory agencies can accumulate hundreds of confidential lawsuits regarding the infractions of concessionaires and his project of law aims to "inhibit opportunistic behaviour" of the concessionaires [109].

Since the Brazilian Health Regulatory Agency (ANVISA) does not insist on the compulsory notification of the failures of orthopaedic implants in Brazil, the problem is not even in the transparency of the agency but lies with its more basic principle of regulatory organization to protect the population [1,49,50]. In this sense, ANVISA is very distant to even implement the transparency of the investigations of failure of implants [66]. Additionally, ANVISA must improve the procedures for the certification and registration of orthopaedic implants [66]. Approval of a product without robust guarantees for safety or efficacy can lead to increased health care costs: first, costs are incurred for ineffective treatment; and second, re-treatment can be even more costly because the untreated disease usually tends to worsen. More dangerous and expensive than ineffective products are products that cause harm. These lead to additional treatment costs, as well as the expense of legal repercussion and remediation [110]. Researchers investigating the main reasons for the refusal of the registration application of generic and similar pharmaceutical drug products by ANVISA pointed out, that this agency incorporate the essence of transparency for these products, but the provision of information is mostly by request and the proactive disclosure of information of the agency is still a challenge [111]. ANVISA's broad mandate and gaps in governance account for disparities in monitoring and assessing the safety of health products. [112].

The Brazilian Government established between 1996 and 2005 at least ten independent regulatory agencies for infrastructure sectors, mostly as part of a privatization program. Although these agencies have institutional guarantees of independence, these guarantees failed to insulate most of these agencies in terms of independence. The independence of regulators comes at a cost for the government and for society. The reason for securing the independence of regulatory agencies is that political control over these agencies may impair their functioning by subordinating them to political decisions. On the other hand, the political control of the agencies to improve the interests of the population and not the private businesses are fundamental, especially for essential infrastructure services, such as health and transport [113]. The transparency of information might play an important role in this trade-off between independency and political control of the regulatory agencies. Unfortunately, Brazil ranks 59 of 69 countries in terms of an international transparency index, probably because the "Access to Information Law" was only issued in 2012 [114]. The challenges to improve the transparency index of the country include the shortfall in the understanding of the transparency law by state and municipal authorities, the recurring requirement for applicants to provide personal data beyond what is determined by law and the high rates of low quality responses to information requests. The report highlighted emblematic cases in which transparency was a central theme for the exercise of basic human rights [115]. Many people believe that the presence of elections alone is not sufficient for a country to be considered democratic and that transparency must be included as part of the definition of political regime. The availability and transparency of policy-relevant data is better in democratic regimes [116].

9. Conclusions

- The transparency of the National Civil Aviation Agency for the investigation of aircrafts accidents in Brazil is recognized as state of the art;
- The transparency of the National Land Transportation Agency for the investigation of railway accidents in Brazil is considered to be inadequate;
- The organization and transparency of the Brazilian Health Regulatory Agency for the investigation of failures of orthopaedic implants is considered to be severely flawed;
- The Brazilian Health Regulatory Agency should take immediate actions to adopt the compulsory notification and investigation of the failures of orthopaedic implants and to implement a reliable certification procedure of the orthopaedic implants after their methodical metrological characterization tests based on the requirements of ISO-ABNT standards;
- The publication of cases of failure analysis is a valuable driving force to improve the transparency of the regulatory agencies.

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