

Chemical and Structural Evaluation of Internal Fixation Materials for Facial Fractures

Francisnele Maria de Aquino Fraporti Tomáz¹, Helder Fernandes de Oliveira^{2,*}, Andreza Maria Fábio Aranha¹, Cyntia Rodrigues de Araújo Estrela¹, Alexandre Meireles Borba¹, Carlos Estrela³, Orlando Aguirre Guedes²

¹Department of Oral Sciences, University of Cuiabá, Cuiabá, Mato Grosso, Brazil.

²Department of Endodontics, University of Anápolis, Anápolis, Goiás, Brazil.

³Department of Stomatologic Sciences, Federal University of Goiás, Goiânia, Goiás, Brazil.

*Corresponding author

Abstract— Oral and maxillofacial injuries often result in fractures of facial bones. The treatment of facial fractures involves the use of plates and screws for internal fixation. This study was aimed at analyzing the surface morphology and chemical constitution of internal fixation materials used to treat facial fractures through scanning electron microscopy (SEM) and energy-dispersive X-ray (EDX) analysis. Twenty-seven plates and 21 screws were distributed in six experimental groups: Group 1- Toride[®]; Group 2- Engimplan[®]; Group 3- MDT[®]; Group 4- Promm[®]; Group 5- Osteomed[®] and Group 6- Stryker[®]. The samples underwent SEM, and the external surface morphology was analyzed qualitatively in images obtained with a magnification of 30-1000X. The surface was described according to its regularity (regular or irregular) and concerning the presence of defects (scratches, corrosion, metal fragments, metal deformation or protuberance [burrs]). Constitutive analysis was made through EDX. The chemical elements were quantified and presented as atomic weight percentages (%p). All the plates presented external surfaces with irregular aspects. Defects were not observed only in Osteomed[®] and Stryker[®] plates. The main components found in the plates were titanium (Ti), silicon (Si) and aluminum (Al). The element phosphorous (P) was found only in Stryker[®] plates. The screws presented regular surfaces and defects on the head and threads. Most of the screws presented Ti and Al peaks. Traces of vanadium (V) were identified in the Stryker[®] and Toride[®] screws. The Promm[®] screws were made of Ti. The analyzed plates and screws presented surfaces with different aspects and defects. Some of the chemical elements found in the plates and screws were not described by their manufactures.

Keywords— Internal fracture fixation, Scanning electron microscopy, Energy-dispersive X-ray spectrometry.

I. INTRODUCTION

Trauma involving the maxillofacial complex represents a significant problem in public health¹. Studies have reported a considerable increase in the incidence of these lesions, with a substantial threat to the quality of life of children, adolescents, adults, and the elderly²⁻⁴.

Oral and maxillofacial injuries often damage soft tissues, teeth, and facial bones²⁻⁴. The mandible is the bone most commonly involved in facial fractures⁵ and internal fixation, an association between plates and screws, is the therapeutic modality usually indicated for resolution of these injuries⁶.

Since its introduction in maxillofacial surgery and traumatology, internal fixation plates and screws have

been the subject of numerous studies that have focused on the analysis of their physical-chemical and biological properties⁷⁻⁹. The interaction of the surgical material with the soft and hard tissues that surround it is strongly influenced by the characteristics of its surface and by its chemical composition⁶. The rigorous quality during manufacturing of plates and screws has been widely discussed¹⁰. Defects on the surface of first-use materials may promote fractures during the installation phase¹¹. Furthermore, preexisting irregularities on the external surface may lead to the failure of the surgical treatment¹².

Plates and screws used for internal fixation are manufactured from different titanium (Ti) alloys¹³. The use of this metal has enabled the development of materials

with excellent physical and mechanical properties⁵, in addition to adequate biocompatibility^{14,15}. However, metallic particles can be released during the handling of these materials and can be lodged in neighboring tissues^{9,16}. There are reports in the literature of tissue pigmentation from Ti mini-plates^{9,10}.

The chemical composition of the material used in the internal fixation, as distributed at the level of its surface structure, can characterize different properties since this surface allows interaction between the material and the tissues with it has contact⁷. Biocompatibility can be directly affected by the chemical composition of the material, since the presence of compounds that irritate the tissues reduces the tissue tolerance to the material⁷. In this way, knowledge of the chemical composition of the internal fixation materials can favor understanding of their biological and physical-chemical properties¹³. A limited amount of information is available about the chemical constitution and the characteristics of the external surfaces of plates and screws before their surgical use. Thus, the present study aimed to evaluate the morphology of the external surface and the chemical constitution of plates and screws used to fix facial fractures.

II. METHOD

Tested materials

The present experiment was an *in vitro* study whose sample consisted of 27 plates and 21 screws from six 2.0 mm internal fixation systems. The tested materials were distributed in six groups, according to their origin: Group 1 - Toride[®] (Tóride Ind.,e Com., Ltda., Mogi Mirim, SP, Brazil); Group 2 - Engimplan[®] (Engimplan Eng.,de Implantes Ind.,eCom. Rio Claro, SP, Brazil); Group 3 - MDT[®] (MDT Ind.,e Com.,de Implantes SA, Rio Claro, SP, Brazil); Group 4 - Promm[®] (Promm Materials

Surgical, Porto Alegre, RS, Brazil); Group 5 - Osteomed[®] (OsteoMed, Dallas, TX, USA); and Group 6 - Stryker[®] (Stryker Corp., Brazil, São Paulo, SP, Brazil). The model and chemical composition of the evaluated materials, according to their manufacturers, are shown in Table I. Scanning electron microscopy (SEM) and energy dispersive x-ray (EDX)

Samples were washed in a dental ultrasonic vat with isopropyl alcohol. Then, they were fixed in stubs, taken directly to the scanning electron microscope (MEV JSM-6610; Jeol Ltda., Tokyo, Japan), which was set at a voltage of 5 to 10 kV and a working distance of 15 mm, and were examined without any preparation or manipulation. The morphology of the external surface was analyzed qualitatively in images obtained with a magnification of 30-1000X. The surface was described according to its regularity (regular or irregular) and concerning the presence of defects (scratches, corrosion, metal fragments, metal deformation or protuberance [burrs])^{12,14}. To determine the defects, a systematic examination of the flat surface, and the screw holes in the plates and the head, and the screw threads was performed. The constituent analysis was performed by energy-dispersive X-ray (EDX) using NSS Spectral Analysis System 2.3 software (Thermo Fisher Scientific Inc., Suwanee, GA, USA). Measurements were made using an acceleration voltage of 25 kV, a beam current of 110 mA, 10⁻⁶Torr of pressure (high vacuum), an analysis area of 130 x 130 mm, an increase of 1000X, and 100 s of acquisition time. Measurements were carried out in three different areas of the plates and the middle area of the screw threads. The elementary analysis (atomic weight percentage [% p] and atomic percentage [% at]) was performed in non-standard analysis mode, using the PROZA correction method (Phi-Rho-Z).

Table I - Model and chemical composition of the internal fixation systems evaluated.

Brand	Internal fixation system		Composition		Production batch
	Plate (n= 3)	Screw(n=3)	Plate	Screw	
Toride [®]	Straight (4 holes)	8 mm	100% Ti	100% Ti	100413
Engimplan [®]	Straight (4 holes)	8 mm	100% Ti	100% Ti	31700
MDT [®]	Straight (4 holes)	6 mm	100% Ti	90% Ti, 4% Al, 6% V	15511N
MDT [®]	Straight (4 holes with intermediate)	10 mm	100% Ti	90% Ti, 4% Al, 6% V	06143Q
Promm [®]	Straight (4 holes with intermediate)	11 mm	-	-	59
Osteomed [®]	Straight (4 holes)	4 mm	100% Ti	90% Ti, 4% Al, 6% V	-
Osteomed [®]	Straight (4 holes with	-	100% Ti	-	-

	intermediate)				
Osteomed®	Curved (6 holes)	-	100% Ti	-	-
Stryker®	Straight (4 holes)	10 mm	-	-	1000015441

Ti - Titanium; Al - Aluminum; V - Vanadium

III. RESULTS

Plates

Figure 1 shows the morphological aspects of the surfaces of the tested plates. All plates had an irregular surface. No cracks were observed. Figure 2 shows the main defects found. Defects were not observed on the surfaces of the Toride®, Osteomed® straight 4-holes, or Stryker® plates. Signs of corrosion were observed only on the Promm® plate.

The main components found are shown in Table II. Essentially, the materials were formed by titanium (Ti), silicon (Si), and aluminum (Al). The phosphorus element (P) was found only on the Stryker® plate. Representative spectra of the EDX analysis are shown in Figure 3.

Screws

Figure 4 shows the morphology of the surfaces of the tested screws. It was found that all screws had regular surfaces. Defects were observed both in the head and in the threads of the Toride®, Engimplan®, MDT®, Promm®, and Osteomed® screws (Figure 5). There were no defects in the Stryker® screws.

Representative spectra of the EDX analysis are shown in Figure 6. Most of the screws showed Ti and Al peaks, and the Promm® screws only consisted of Ti. Traces of vanadium (V) were identified in the Stryker® and Toride® screws, while the P element was shown only in the Stryker® screws.

Table II - Chemical elements (mean and standard deviation) observed on the plates using energy dispersive X-ray (EDX).

Plates	Chemical elements							
	Al		P		Si		Ti	
	%p	%at	%p	%at	%p	%at	%p	%at
Toride®	0.07 ±	0.13 ±	-	-	0.10 ±	0.18 ±	99.82 ± 0.13	99.69 ± 0.23
	0.10	0.19			0.15	0.15		
Engimplan®	0.85 ±	1.50 ±	-	-	0.71 ±	1.18 ±	98.44 ± 0.76	97.32 ± 1.28
	0.24	0.41			0.53	0.89		
MDT®	-	-	-	-	-	-	100.00 ±	100.00 ±
							0.00	0.00
MDT®***	-	-	-	-	-	-	100.00 ±	100.00 ±
							0.00	0.00
Promm®	2.58 ±	4.43 ±	-	-	1.84 ±	3.04 ±	95.57 ± 0.87	92.53 ± 1.49
	1.49	2.52			0.63	1.06		
Osteomed®	0.37 ±	0.64	-	-	2.77 ±	4.61 ±	96.86 ± 0.78	94.75 ± 1.29
	0.07	±0.12			0.72	1.18		
Osteomed®*	0.20 ±	0.34	-	-	1.55 ±	2.60 ±	98.25 ± 1.18	97.05 ± 1.96
	0.16	±0.27			1.02	1.70		
Osteomed®*	0.15 ±	0.26 ±	-	-	0.52 ±	0.88 ±	99.33 ± 0.40	98.86 ± 0.70
	0.21	0.36			0.22	0.38		
Stryker®	0.15 ±	0.26 ±	0.43 ± 0.31	0.67 ±	-	-	99.52 ± 0.36	99.24 ± 0.56
	0.21	0.36		0.47				

%p - percentage of atomic weight; %at - atomic percentage; *** 4-holes MDT plate with intermediate; ** Osteomed 4-holes curved plate; * Osteomed 4-holes plate with intermediate; Al - aluminum; P - phosphorus; Si - silicon; Ti - titanium.

IV. DISCUSSION

Information on the surface characteristics and chemical composition of surgical materials represents a

predictive factor for understanding their physical-chemical and biological properties^{12,13,17}. Knowing the morphology of the external surface and the chemical composition of

plates and screws used in the internal fixation of facial fractures will help in the selection of the best material to be used¹⁸.

Quality control of the materials used to treat facial fractures is essential¹⁹. The absence of surface defects is expected when acquiring and using these materials since it is impossible to detect them macroscopically. The results of the present study showed the absence of defects (scratches, corrosion, metal fragments, metal deformation, or protuberances [burr]) in the Toride[®], Osteomed[®], and Stryker[®] plates and in the Stryker[®] screws when analyzed by SEM. However, the Engimplan[®], MDT[®] and Promm[®] plates, and the Toride[®], Engimplan[®], MDT[®], Promm[®], and Osteomed[®] screws showed defects, as also observed in other studies^{14,17,18}. Matthew et al.¹⁸ evaluated the surface mini-plates and screws of Champy made of stainless steel and Ti and used in the treatment of mandibular fractures. Irregularities such as craters, cracks, and depressions were found on the surfaces of mini-plates that had been surgically removed. These irregularities were similar to those found on the surface of the control group's mini-plates, which suggests that these failures may be due to the manufacturing process. Damage to the surface of the screws due to manipulation was also observed. Some irregularities were found in the head of the screws in the control group. Trivellato et al.¹⁷ performed a macroscopic study of the Ti plates and screws of the Engimplan[®], Bucomax[®], Synthes[®], and W. Lorenz[®] systems. The authors concluded that the Engimplan and Bucomax systems showed terrible behavior concerning the standardization of their plates and screws' dimensions. Langford and Frame¹⁴ evaluated the surfaces of Ti plates and screws used in maxillofacial surgery. Manufacturing defects were found in four of the 18 plates and two of the 10 screws. These defects consisted of rough edges and metal protuberances located over the screw heads and around the screw holes. It is important to highlight that the tested material have distinctive manufacturing process, which may justify the presence of plates and screws with varying quality standards.

The regularity of the surface represents a critical aspect commonly related to the adhesion of cells to the material, a fundamental factor in evaluating biocompatibility of biomaterials^{11,20}. SEM is an essential tool in studying the size and distribution of particles or granulations present on the external surfaces of dental materials^{21,22}. In the present study, the surfaces of the plates and screws were qualitatively evaluated. The analysis revealed that all the plates showed external surfaces with irregular features, especially the Toride[®] plate. However, no cracks were observed on the surfaces of the studied

materials. In a previously published study, several cracks on the surfaces of surgically removed plaques were observed¹⁸. Krischak et al.²⁰ compared the corrosion and metal release rates between stainless steel plates and Ti-CP used in osteosynthesis in orthopedics. Stainless steel plates showed a greater extent of deterioration. The absorption of the measured ions increased after they were used, with high concentrations of iron (Fe), chromium (Cr), nickel (Ni), and molybdenum (Mo) being observed. No material caused a foreign-body reaction in local tissues.

The screws analyzed in this study showed regular surfaces. Thus, one can expect better results in terms of cell adhesion in these materials⁹. However, it is worth noting that other factors also affect cell adhesion and the biocompatibility of a material, such as its chemical composition⁷. This fact points out that the surface regularity of data should not be analyzed in isolation. The mapping of the components allows us to reveal the elements distributed along the external surfaces of the materials, which can maintain direct contact and influence the characteristics of the tissues' biological responses.

EDX is a reproducible and accurate method that allows qualitative and quantitative analysis of the main components or compounds present in a material or association of materials²¹. This methodology is based on the interaction between particles (electromagnetic radiation) and matter and analyzes the emitted X-rays²². Each chemical element has a unique atomic structure so that the emitted X-rays are characteristic of that structure and identify a given element^{23,24}. However, EDX has some limitations. In some cases, the interpretation of results may be hampered by continuous radiation or the overlapping of chemical elements²³. Also, the proportion of ionizing events, which result in the emission of X-rays, decreases as the number of the element's atomic weight becomes smaller. Thus, the quantification of organic compounds, which contain carbon, oxygen, and hydrogen, cannot be performed with precision²⁴.

EDX microanalysis revealed the existence of a similarity between the Toride[®], Engimplan[®], Promm[®], and Osteomed[®] plates regarding the presence of Ti, Al, and Si (Table II). This finding is consistent with the results obtained by other studies that compared the chemical composition of these materials and observed small variations between them^{9,14,17}. Regarding the screws, most showed peaks of Ti and Al. Traces of V were identified in the Stryker[®] and Toride[®] screws, while the element P was evidenced only in the Stryker[®] screw. The presence of element V is justified by the type of alloy used. The

screws are generally made with Ti6Al4V alloy, which according to the ASTM F 1108-97²⁵ and ISO/DIS 5832-3²⁶ standards, provide more excellent resistance to flexion when compared to grade 1 pure titanium alloys. Silva et al.²⁷ highlighted that the combined use of commercially pure titanium and Ti6Al4V alloy is contraindicated due to the possibility of galvanic corrosion.

Elements that were not described in the manufacturers' composition base were identified. The Toride[®], Promm[®], and Osteomed[®] plates showed traces of Si. Traces of P were observed on the Stryker[®] plates and screw traces. These results can be attributed to contamination during the manufacturing or even while in the market reserve.

Several elements have been considered aggressive to human cells in specific concentrations such as Al⁸. Except for the MDT[®] plate, this element was found in all the tested plates, which justifies the results suggestive of cytotoxicity or genotoxicity¹⁶.

The results of this study provide an understanding of the interactions between internal fixation materials and facial tissues. Such knowledge should help develop new materials with well-defined properties, for a wide variety of applications in surgery and oral and maxillofacial traumatology.

V. CONCLUSION

With the methodology used, it was possible to conclude the following:

1. The analyzed plates and screws showed surfaces with different aspects and defects.
2. There was a discrepancy between the elements found and the main elements described by the manufacturers.

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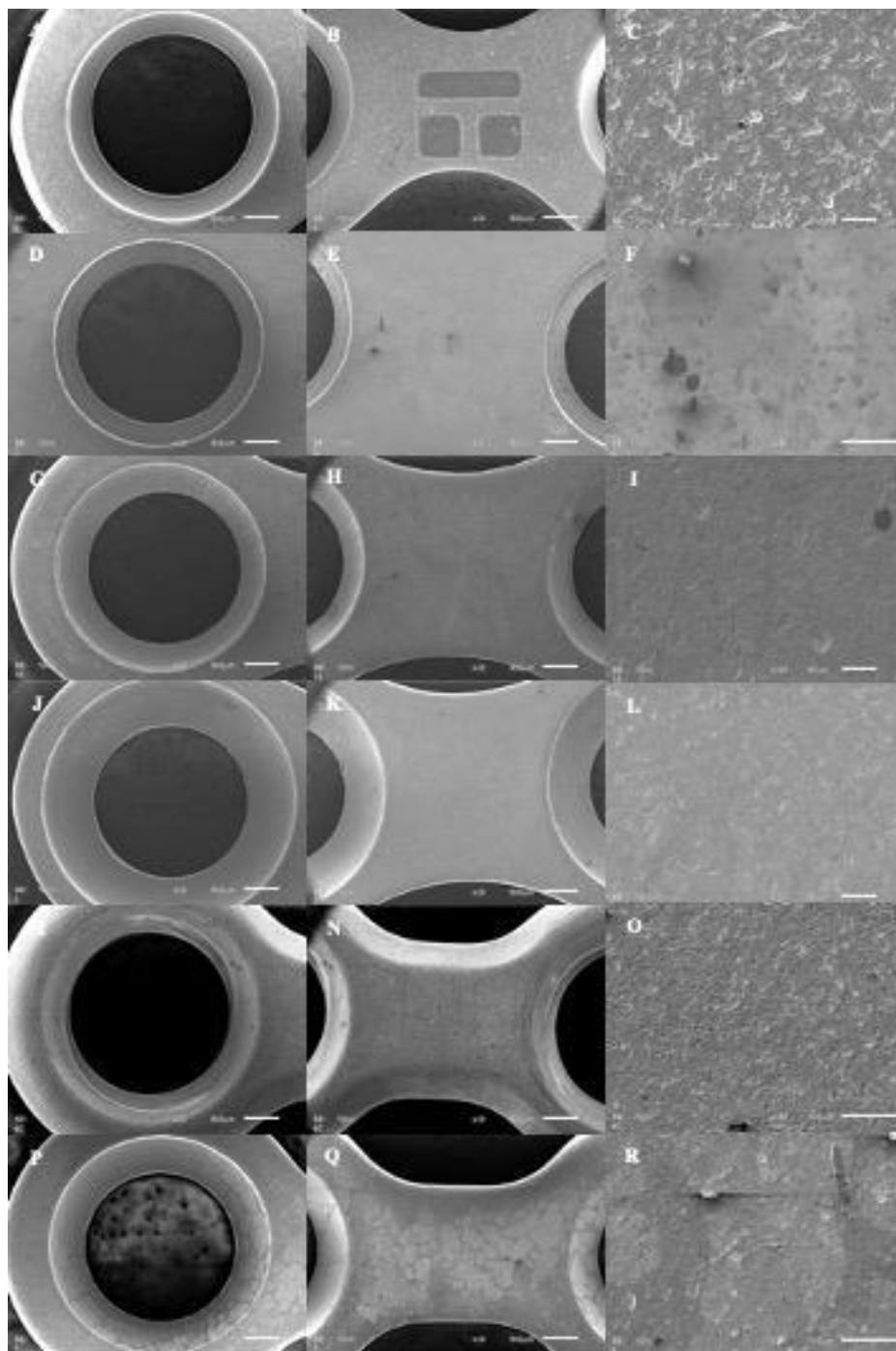


Fig.1 -SEM images showing morphological aspects of the surfaces of the tested plates. Toride®: (A) screw insertion hole at 30X; (B) flat surface at 30X and (C) surface irregularity at 300X; Engimplan®: (D) screw insertion hole at 30X; (E) flat surface at 30X (F) surface irregularity at 250X; Straight MDT®: (G) screw insertion hole at 30X; (H) flat surface at 30X and (I) surface irregularity at 300X; Promm®: (J) screw insertion hole at 30X; (K) flat surface at 30X and (L) surface irregularity at 300X; Osteomed® straight with intermediate: (M) screw insertion hole at 30X; (N) flat surface at 30X and (O) surface irregularity at 250X; Stryker®: (P) screw insertion hole at 30X; (Q) flat surface at 30X and (R) surface irregularity at 250X.

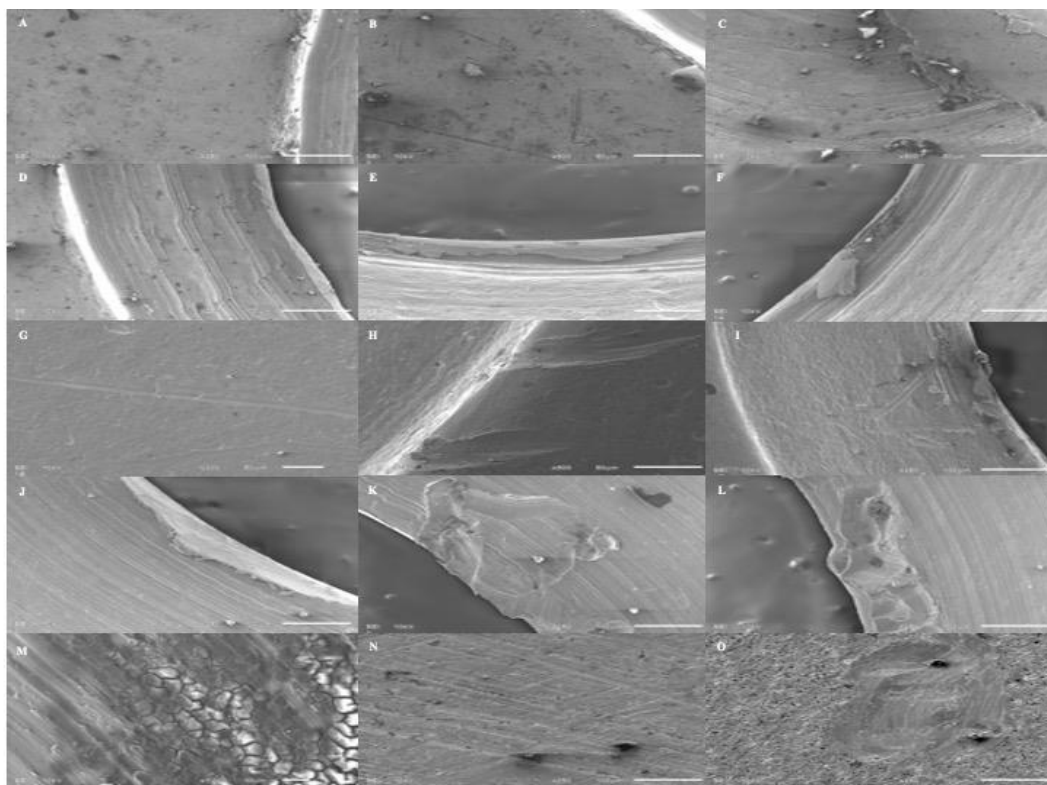


Fig.2 -SEM images of defects found on the flat surface and holes in the plates. Engimplan®: (A) metal fragments at 250X; (B) scratches and metal fragments at500X; (C) burrs and metal fragments at250X and (D) deformation and metal fragments at500X; Straight MDT®: (E) and (F) burrs at 250X; Straight MDT® with intermediate: (G) scratches at 300X and (H) scratches at 500X and (I) scratches and burrs at 250X; Promm®: (J) deformation and burrs at 250X; (K) and (L) deformation and metal fragments at250X and (M) area of corrosion at1000X; Osteomed® curved: (N) scratches at250X and Osteomed® straight with intermediate: (O) deformation at250X.

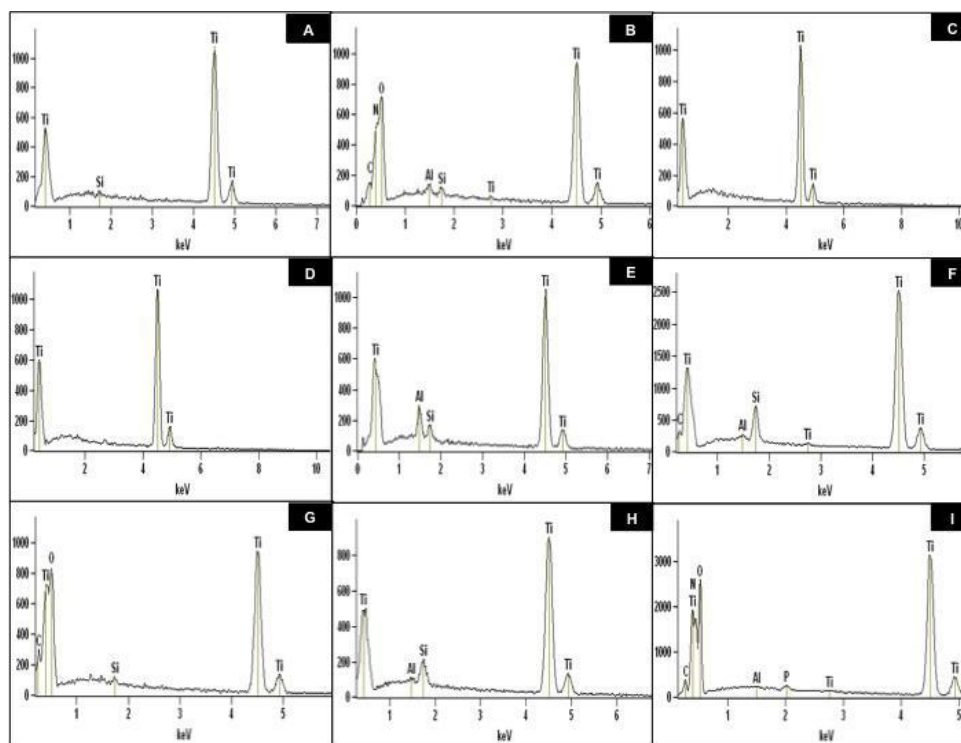


Fig.3 - Representative EDX spectra of the tested plates: (A) Toride®; (B) Engimplan®; (C) MDT® straight; (D) MDT® with an intermediary; (E) Promm®; (F) Osteomed® straight; (G) Osteomed® curved; (H) Osteomed® with an intermediate; and (I) Stryker®.

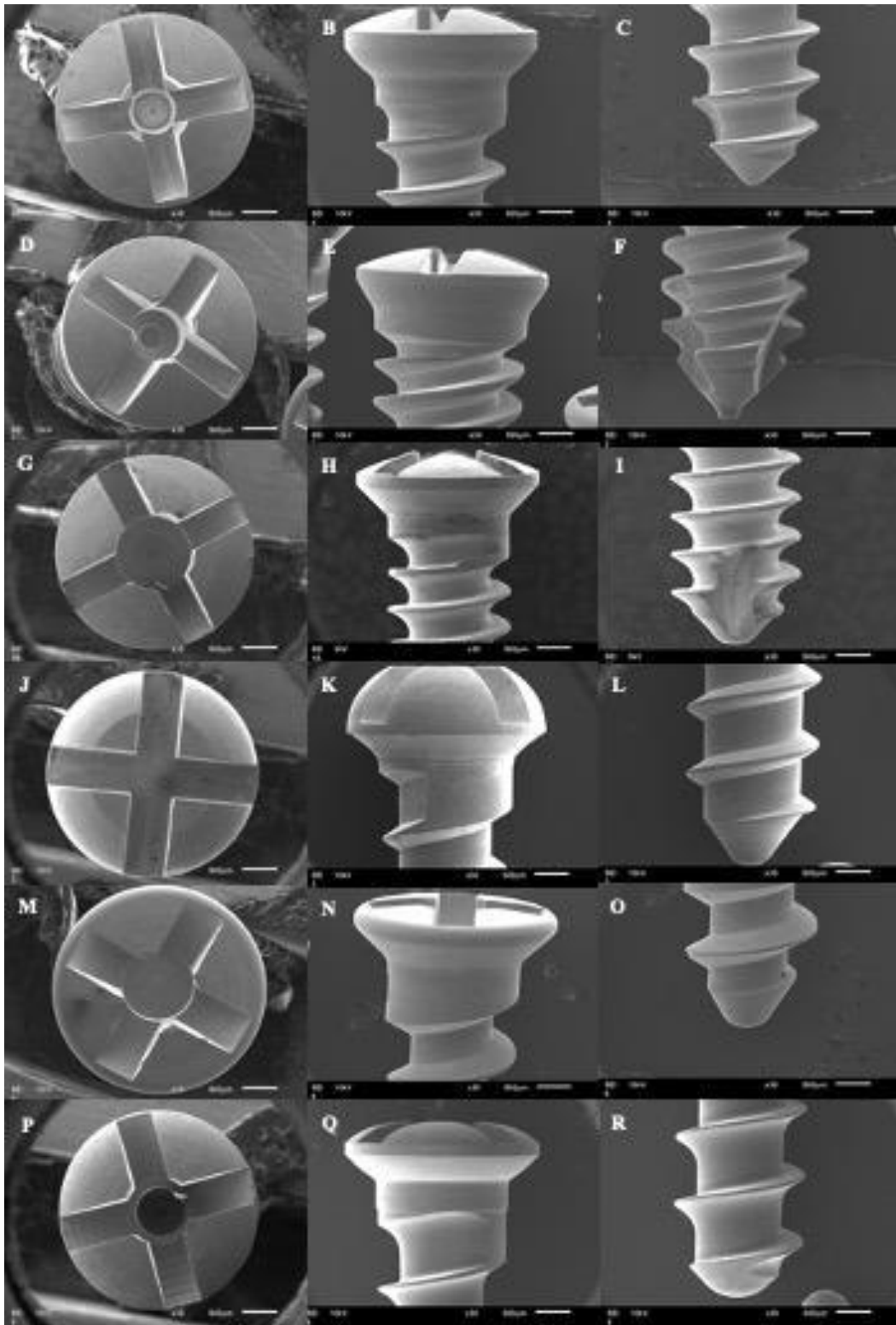


Fig.4 -SEM images at 30X magnification, showing the morphological aspects of the tested screw surfaces: head and body (thread). Toride[®]: (A), (B), and (C); Engimplan[®]: (D), (E), and (F); MDT[®]: (G), (H), and (I); Promm[®]: (J), (K), and (L); Osteomed[®]: (M), (N) and (O); and Stryker[®]: (P), (Q), and (R).

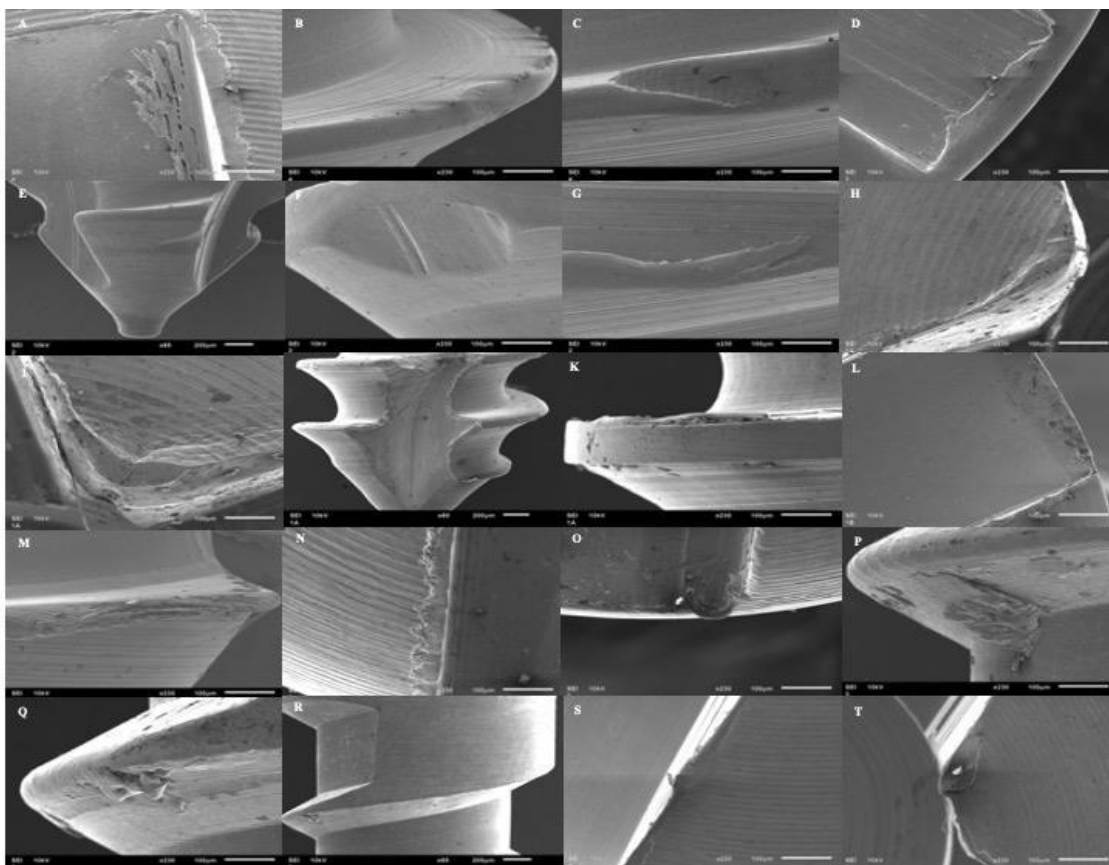


Fig.5 -SEM images of defects found in screw heads and threads. Toride[®]: (A) burrs and fragments of metal at 230X; (B) and (C) deformation at 230X; Engimplan[®]: (D) and (E) burrs and deformation at 65X; (F) deformation at 230X; (G) burrs at 230X;MDT[®] 6mm: (H) metal fragments at 230X; (I) deformation and metal fragments at230X; (J) burrs and deformation at 60X and (K) burrs and metal fragments at 230X; MDT[®] 10mm: (L) and (M) burrs and metal fragments at230X; Promm[®]: (N), (P) and (Q) burrs at 230X and (R) metal fragments at 65X; and Osteomed[®]: (S) deformation and metal fragments at230X and (T) metal fragments at230X.

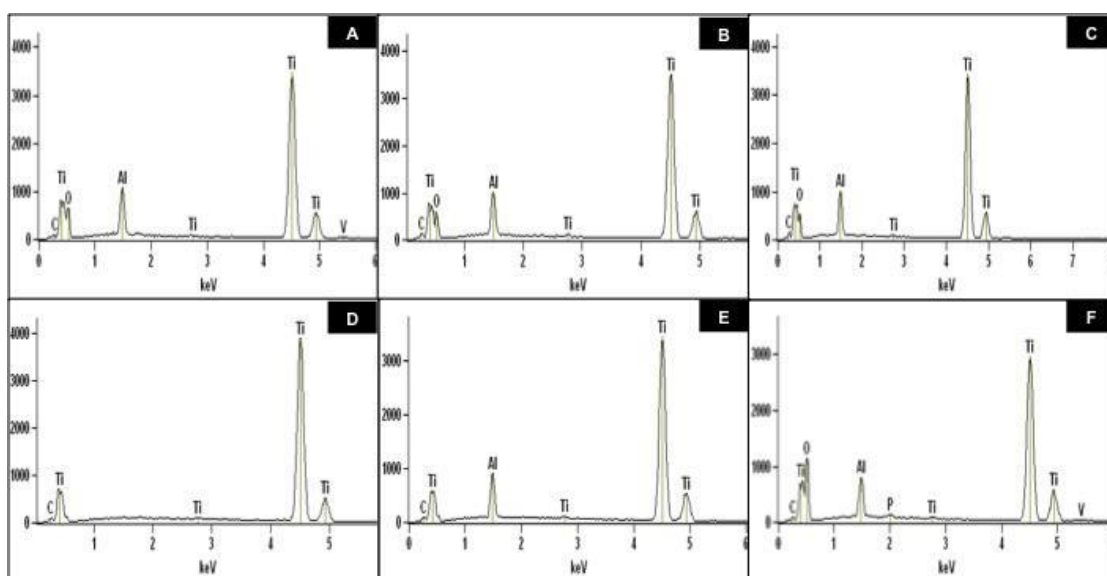


Fig.6 - Representative EDX spectra of the tested screws: (A) Toride[®]; (B) Engimplan[®]; (C) MDT[®]; (D) Promm[®]; (E) Osteomed[®]; and (F) Stryker[®].