

The Physical, Chemical and Biological Evaluation of Commercially Available Metal Orthodontics Brackets: *In vitro* Study

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Abstract

Aim: This *in vitro* study was done to evaluate the physical, chemical and biological properties of 4 brands of metal orthodontics brackets.

Objectives: To analyse the physical, chemical, composition, the corrosion resistances, nickel ion release and cytotoxicity of the orthodontics brackets.

Materials and Methods: 4 bracket were tested for dimensional accuracy of orthodontics brackets namely group-1: Gemini (3M Unitek), group-2: Ecoplus (Chirpans orthodontics), group-3: Monalisa (JJ orthodontics), group-4: Sapphire (Modern orthodontics). Manufacturing errors in angulation and torque, cytotoxicity, composition, elution and corrosion.

Results: The tested brackets showed no significant difference in manufacturing errors in angulation, but sapphire brackets showed a significant difference in manufacturing errors in torque. Gemini brackets offered better corrosion resistances and showed the least nickel release among all the groups. Cytotoxicity tests showed that gemini is the least cytotoxic and ecoplus is the most cytotoxic.

Conclusion: The results of this study could potentially be applied in establishing national standards for orthodontic brackets and in commercially available products.

Keywords: Orthodontic brackets; Cytotoxicity; Corrosion resistances; Scanning electron microscopy

Introduction

Orthodontic brackets were introduced in the mid 1980's in India and now days expensive products manufactured in the US, Japan, and Germany are commonly used in most dental clinics. Domestic manufacturing started to produce and sell orthodontics brackets in the early 2000's. Moreover, brackets manufacturing overseas that not yet verified are being imported and distributed in the country. Despite these development, national standards for such products have not been established and international standard explain only the related terms but not regulate detailed requirements [1].

Stainless steel is one of the most popular materials used for orthodontics brackets, because Stainless steel possess an excellent level of anti-corrosion, metal orthodontics brackets can corrode upon exposure to potentially harm full physical, and chemical substances in the oral cavity for several months or even several years [2,3].

The recent times has seen as emergence of a wide variety of brands manufacturing and marketing Stainless steel brackets. Corrosion reduces the volume of orthodontic brackets, subsequently decreasing orthodontics forces, and causing cracking in areas of stress concentration [4]. Chromium, in the presence of air (oxygen) forms a thin film of chromium oxide which covers the surface of the stainless steel. Chromium oxide is the inert or passive by nature, and chromium in the material gives stainless steel its corrosion resistant properties [5].

Nickel ion release secondary to corrosion also results in fracture of orthodontic brackets, poor clinical outcomes, local hypersensitive reactions, and general deterioration of health when toxic products are absorbed locally or systemically [6]. This *in vitro* study was performed on different brands manufacturing stainless steel brackets to evaluate the physical, chemical and biological properties of commercially available metal orthodontics brackets.

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Materials and Methods

Brackets

Five upper central incisor brackets were taken 4 brands of commercially used metal orthodontic brackets manufacturing in different countries were tested.

Group 1: Gemini (3 M Uniteck, Monrovia, USA)

Group 2: Ecoplus (Chirpans orthodontics, China)

Group 3: Monalisa (JJ Orthodontics, India)

Group 4: Sapphire (Modern Orthodontics, India)

Dimensional accuracy test

Dimensional accuracy test to determine whether the brackets meet the criteria stated by the manufacturers. Five upper central incisor brackets per brand (n=20) were randomly selected and measured for angulation, torque, and manufacturing errors in these parameters. To evaluate angulation, the faces of the brackets were photographed by optical microscopy at a magnifying power of 25 and their angulations were measured with a computer-based measuring tool.

Each band checked for physical, chemical, corrosion resistances, Ni-ion release and cytotoxicity. To evaluate torque, the samples were embedded in epoxy resin to minimize measurement errors due to the curvature of the bracket base, and the profiles were obtained by Micro grinding and the standard values were divided by the standard values to determine manufacturing errors in angulation, torque and the resultant values were charted [7].

Cytotoxicity analysis

Of 12 samples of each brand was analyzed with a quantitative test: MTT assay and also qualitative test, wire-dead assay.

Compositional analysis

The composition of the brackets from the 4 brands was analyzed by inductively coupled plasma atomic emission spectrometry (Optima 3000, Perkin Elmer, and Wellesley, MA, USA).

Elution test

The elution of metal ions from the brackets over time was analyzed in artificial saliva (PH 6.5) produced by the Fusayama-Meyer method. Nickel ion release was assessed at 24 h, 7 days, 14 days, 28 days by ICP-MS (Inductively Couple Plasma Mass Spectrometry).

Corrosion analysis

Corrosion resistances of 12 samples of each brand was assessed by potentio dynamic polarization device (CH-Analyser).

Statistical analysis

Data are expressed as means (standard deviation) SPSS for windows (version 12.0 SPSS Inc, Chicago, IL, USA) was tested for statistical analysis). ANOVA and pair wise comparisons with post hoc tukey test.

Results

Table 1 shows that angulation was not significantly different among the products, because the standard values of the manufacturers were similar. Group 4 brackets showed a difference in torque, however, this difference was not interpreted as manufacturer was different. Table 2 shows the deviation (manufacturing error) of the measured values from the standard values. Group 2 and group 4 brackets showed the largest deviation in angulation and torque respectively. Although the differences in torque was significant ($p < 0.05$), the difference in angulation was not [8]. Compositional analysis test shows that Table 3 showed that iron, chromium and nickel were predominantly present in all the 4 brands. Other trace elements like silicon, Al, Cu, Ag, Carbon and oxygen were found in some brands. The mean value among the 4 groups for iron analyzed by one way ANOVA is statistically significant. The mean value among the four groups four chromium analysed by one way ANOVA is statistically significant (Table 4). The mean value among the four groups for nickel analysed by one way ANOVA is statistically significant (Table 5).

Table 1: Data of anugulation and torque.

Group	Angulation (o)		Torque		N
	Means	SD	Means	S.D	
Group 1	5.52	0.32	16.38	0.46	5
Group2	4.45	0.48	16.15	0.49	5
Group 3	4.42	0.33	17.07	0.6	5
Group 4	5.6	0.49	13.85	0.13	5

Table 2: Data of manufacturing errors in angulation and torque.

Group	Angulation relative error (%)		Torque-relative error (%)		N
	Mean	S.D	Mean	S.D	
Group 1	10.4	6.43	3.37	2.48	5
Group 2	13.04	9.59	5	2.86	5
Group 3	10.58	8.33	2.64	2.03	5
Group 4	12.06	9.71	15.44	1.09	5

Table 3: Iron concentration.

Group	Mean	S.D	F value	P value
Group 1	70.28	3.7	4.135	0.011*
Group 2	68.35	5.78		
Group 3	68.02	0.94		
Group 4	72.68	2.3		

Note: *Statistical significance at p<0.05

Table 4: Chromium concentration.

Group	Mean	S.D	F value	P value
Group 1	18.92	0.75	11.469	<0.0001*
Group 2	68.35	1.8		
Group 3	68.02	1.05		
Group 4	72.68	1.03		

Note: *Statistical high significance at p<0.05

Table 5: Nickel concentration.

Group	Mean	S.D	F value	P value
Group 1	8.88	3.56	17.213	<0.0001*
Group 2	4.72	1.03		
Group 3	4.13	0.47		
Group 4	4.26	0.54		

Note: *Statistical significance at p<0.05

The polarization curves were plotted in the potential range of +400 mV to -400 mV at a scanning rate of 0.01 V/s. The I_{corr} , rate/yr and polarization resistance values obtained are as follows. There is no statistical significance among the brands. The I_{corr} (current density) for the 4 groups are tabulated as follows (Table 6). According to one way ANOVA, Group 3 shows the highest current density among the 4 groups. The rate of degradation of the metal/year is tabulated in Table 7. One way ANOVA Shows that Group 3 the highest rate of

degradation/year, which indicates its susceptibility to corrode [9].

Polarisation resistance among the 4 groups is tabulated in Table 8. Group 1 shows the highest resistance with indicates its resistance to corrosion. Although there is a difference in value among the 4 groups in case of I_{corr} , Rate/yr, and R_p , it is not statistically significant, according to one way ANOVA.

Table 6: I_{corr} values obtained from the four brands.

Group	Mean ($\times 10^{-8}$)	S.D	F value	P value
Group 1	3.41	1.38	1.089	0.364
Group 2	4.28	2.63		
Group 3	4.66	2.61		
Group 4	3.27	2.08		

Table 7: Rate of degradation of the metal/year.

Group	Mean ($\times 10^{-8}$)	S.D	F value	P value
Group 1	3.54	1.37	1.152	0.339
Group 2	4.73	3.03		
Group 3	5.06	2.79		
Group 4	3.63	2.39		

Table 8: Polarisation resistances.

Group	Mean (ohms)	S.D	F value	P value
Group 1	5342.45	3218.04	2.224	0.087
Group 2	285.25	1705.42		
Group 3	375.4	1662.92		
Group 4	3380.42	2756.75		

Nickel release over four time durations *i.e* 24 hours, 7 days, 14 days and 28 days was evaluated. The mean values of the four groups at 24 hours was tabulated (Tables 9 and 10) and is statistically significant, according to one way ANOVA. Group 3 shows the highest ion release in 24 hours. The live dead assay shows live cells as green and dead cells as red (Table 11). In the study, it was found that Group 2 has shown the maximum number of dead cells as compared to the other

brands and is thus shown to be cytotoxic, whereas, group 1 has the least number of dead cells and thus it is shown to be least cytotoxic. In the MTT assay, it is also the reflecting the same results as the qualitative analysis which is statistically significant, with Group 1 showing the maximum amount of cell viability, with Group 2 showing the least cell viability (Tables 12 and 13).

Table 9: Nickel release over 24 hr.

Group	Mean	S.D	F value	P value
Group 1	3.5	0.83	224.084	0.0001*
Group 2	156.5	18.16		
Group 3	379.16	51.21		
Group 4	51.66	5.81		

Note: *Statistical significance at $p < 0.05$

Table 10: Nickel ion release after 7 days.

Group	Mean	S.D	F value	P value
Group 1	4.83	2.13	679.53	0.0001*
Group 2	177	15.19		
Group 3	861.8	58.38		
Group 4	247.16	35.68		

Note: *Statistical significance at $p < 0.05$

Table 11: Nickel ion release after 14 days.

Group	Mean	S.D	F value	P value
Group 1	3.5	1.37	86.448	0.0001*
Group 2	137.5	17.16		
Group 3	157.6	22.84		
Group 4	161.83	27.28		

Note: *Statistical significance at $p < 0.05$

Table 12: Nickel ion release after 28 days.

Group	Mean	S.D	F value	P value
Group 1	2.5	0.83	93.861	0.0001*
Group 2	109.83	10		
Group 3	132.83	17.64		
Group 4	131.5	23.89		

Note: *Statistical significance at $p < 0.05$

Table 13: Cell viability among the four groups.

Group	Mean	S.D	F value	P value
Group 1	102.9339	6.6134	260.3136	0.0001*
Group 2	33.6729	6.5816		
Group 3	37.8188	8.1364		
Group 4	47.7246	6.1034		

Note: *Statistical significance at $p < 0.05$

Discussion

All dental materials must be biocompatible and orthodontic brackets, which are in direct contact with teeth and are exposed to saliva, should not contribute to any toxicity due to metal ion release from their surfaces. Brackets act as handles to transmit the force from the active components to the teeth. Brackets have one or more slots that accept the arch wire. In the present study about 10.4%-13% of the brackets showed manufacturing errors in angulation and two group brackets

appeared to have the largest, deviation from the standard values, though this finding was not significant. Furthermore, about 2.6%-15.4% of the brackets showed manufacturing errors in torque and group 4 brackets (Sapphire) showed that longest deviation, which was significant. In the present study, all the 4 brands showed predominantly Fe, Nickel and Chromium. Gemini (3M) brackets showed the presence of silicon and traces of aluminium. Ecoplus (Chirpans orthodontics) has shown presence of silicon, with traces of copper and carbon. Monalisa (JJ orthodontics) showed

silicon with traces of copper and oxygen. Sapphire (Modern orthodontics) has shown traces of copper and silver [10].

Stainless steel's high resistance to corrosion is mostly due to the significant amount of chromium present. Chromium oxide forms a passive layer over the surface of the steel, preventing oxygen from penetrating the alloy. Nickel forms salts that prevent chromium salts from forming, which leaves more chromium to form the passive layer. Nickel also provides firmness and ductility to stainless steel and acts as an austenite stabilizer, making the austenitic form more stable at lower temperatures. Oh et al. evaluated various physical and chemical properties of custom-made bracket and commercially available brackets, but their analysis of dimensional accuracy was limited to the slot size and horizontal and vertical dimensions of the bracket wing, which are relatively easy to measure. Angulation and torque of the bracket slot, which are complicated parameters, were measured in the present study. About 10.4%-13% of the brackets showed manufacturing errors in angulation and group 2 brackets appeared to have the largest, deviation from the standard values, though this finding was not significant. Furthermore, about 2.6%-15.4% of the brackets showed manufacturing errors in torque and group 4 brackets showed the largest deviation, which was significant. Nonetheless, inaccuracy of the tangential, perpendicular, and median lines drawn for the measurements and distortion of facets due to 2-dimensional photography should be considered and accounted for while interpreting the results [11,12].

Since this study is an *in vitro* test, artificial saliva proposed by Fusayama et al. was used as the electrolyte for the corrosion test. Marek reported that Meyer and Nally examined the behaviour of several dental alloys in natural saliva, Ringer solutions, and five different synthetic saliva, indicated that, among those tested, that proposed by Fusayama et al. produced results most closely approximating those in natural saliva. In this study, the corrosion resistance of the four brands of orthodontic brackets were analysed by using a potentiodynamic polarization device. Gemini brackets exhibited the highest polarization resistance (R_p), followed by monalisa brackets, then sapphire brackets, with the least R_p shown by ecoplus brackets which indicates that among the four companies, ecoplus brackets shows the highest tendency to corrode. There could be many reasons for corrosion to occur on stainless steel brackets.

However, group 3 products appeared to have a significant larger total elution volume possibly due to excessive elution of Ni, metallic corrosion is influenced by various factors such as intraoral PH, dental plaque and its secondary products, and oral flora, temperature, internal stress, friction of brackets and wires due to constant movements. According to Fraunhofer, stainless steel exhibits pitting corrosion in chloride media. The artificial saliva in which the brackets were tested for corrosion resistance contained chloride, which could explain the corrosion of the stainless steel. Studies have shown that stainless steel will release nickel ions after corrosion occurs, a disadvantage with stainless steel bracket corrosion concerns patients with allergies to

nickel and other specific substances. Of known metals, nickel is the most allergenic. Nickel sensitivity has an incidence between 10% to 20% of the population and nickel is also the most common metal associated with contact dermatitis in orthodontics. Common oral manifestations of a nickel allergy include a burning sensation, glossitis, gingivitis, gingival hyperplasia, metallic taste. Kerosuo et al. demonstrated, *in vitro*, that metal brackets experiencing orthodontic forces release more nickel and chromium than brackets free of orthodontic force [13].

Freitas et al. used stainless steel orthodontic wires as a negative control group (nontoxic group) to assess the cytotoxic impact of silver solder on fibroblasts. Although various metallic materials may not initially display any cytotoxicity in the form of finished products, they may eventually become cytotoxic when exposed to the oral environment for extended periods and metal ions are released. In this study, nickel ion showed a peak after 7 days, which gradually declined by day 28 in all the four brands. Gemini brackets showed the least nickel ion release among the four brands. Another feature that was noted among the brands, was that nickel ion release increased by the end of one week among all the brands, but when we consider any one particular brand, the rate of increase or decrease is not consistent. This is in accordance with a previous study done. To determine *in vivo* release of nickel and chromium ions in conventional and self-ligating brackets in un stimulated saliva at four time intervals, Nickel and chromium released into saliva from conventional and self-ligating brackets progressively increased from days 1-7 and then decreased at day 30. It has been shown in a study that there is no proportional relation between the release of nickel ions and the nickel content of orthodontic brackets and wires.

A significant increase in Ni and Cr level in saliva and it reached the highest level in 1st week. This was similar to the results of Park and Shearer who evaluated conventional brackets, and reported that the nickel and chromium releases reached a plateau after 6 days. An *in-vitro* study found that nickel release reached a maximum after 1 week and then diminished. Nickel and chromium concentrations of saliva are not significantly affected by fixed orthodontic appliances during the first month of treatment. Another study was done by who also did not find any differences in nickel amounts in saliva before and 3 weeks after insertion of fixed appliances. However, a significantly increased nickel concentration in saliva samples taken immediately after placement of the appliances in a group of six cases. Investigated the effects of dental alloys containing Ni on the level of this element in the serum, liver, kidney, and oral mucosa of guinea pigs. Statistically significant differences were found between liver and oral mucosa Ni content in the experimental and control groups. The cytotoxicity from a corroded metal orthodontic appliance is an important issue. Corrosion releases metal ions into the oral cavity that are ingested into the gastrointestinal system.

Locally, the released ions may adversely affect the oral tissues by inhibiting enzyme or mitochondrial activity and

damaging DNA, as has been demonstrated *in vitro*. Moreover, chromium and nickel ions may induce type IV hypersensitivity. In this study, cytotoxicity of the orthodontic brackets were assessed by a qualitative test (live- dead assay) and a quantitative test (MTT assay). The test showed that gemini brackets were the least cytotoxic and ecoplus was the most cytotoxic. A previous study was indicated no ionic release for the nickel titanium alloy aging solution, whereas measurable nickel and traces of chromium were found in the stainless steel bracket aging medium. In this study, monalisa brackets showed the highest nickel ion release and ecoplus brackets have shown more cytotoxicity. This could be attributed to the fact that in this study, nickel ion release was checked in artificial saliva and cytotoxicity was checked on cultured fibroblast cells. Standard quality products thus ensure a safer and better treatment of the patients with the least side effects. This study showed that standardization plays a very important role in the manufacturing of orthodontic brackets. Furthermore research by *in vivo* studies could guarantee a better insight to the results obtained from this study.

Conclusion

From the present *in vitro* study on orthodontic brackets, the following conclusion has been through dimensional accuracy measurements, no differences were found between the products in manufacturing errors of angulation, but group 4 showed a significant difference in manufacturing errors of torque ($p < 0.05$). Nickel concentration is highest in Gemini brackets as compared with the others. The corrosion resistance measured shows that monalisa is the least corrosion resistant and gemini brackets are highly resistant to corrosion, but these values are not statistically significant. Gemini brackets showed the least ion leach among the four brands. Gemini brackets showed the highest cell viability and therefore is least cytotoxic and ecoplus brackets showed the least cell viability and hence, is the most cytotoxic.

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