Comparative Evaluation between locally manufactured Egyptian and International Implant Systems Used in Mandibular Overdenture Cases

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Abstract: Objective: To evaluate and compare clinically, radiographically and laboratory between locally manufactured Egyptian and international implant systems used in mandibular overdenture cases. **Material and Methods:** Eighteen systematically healthy edentulous patients were participating in this study to receive mandibular implant overdenture retained by two implants in the canine area. Six implants were also used for laboratory evaluation of dental implant material. Patients were divided into three groups (A, B and C). Six patients for every group. *Group A*: (control group) patients received two reputable international, titanium, threaded endosseous implants (Prodigy), *Group B*: patients received two locally manufactured, titanium, threaded endosseous implants (EDIM-II), and *Group C*: patients received two locally manufactured, titanium, threaded endosseous implants (Tut-II). Clinical and radiographic evaluations were carried out for every patient at the time of loading, then six month intervals up to one year from functional loading. Complications of the abutments and overdentures are carefully checked and reported for prosthetic evaluation. Also, the surgical kit of each implant system was evaluated. Two laboratory tests were performed to determine the chemical composition of implant fixture using scanning electron microscopy-energy dispersive spectroscopy detection method (SEM-EDS), the other microbiological analysis test was done to check the sterilization and sealing of implant package. **Results & conclusion:** Locally manufactured Egyptian implants could be accessible to many patients who seek low cost dental implants and could not pay for international types of dental implants due to their high cost. The Egyptian manufacturers should overcome the problems pointed in our study and consider our recommendation to improve their products.

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Keyword: dental implants, mandibular implant overdenture, Biohorizon implants.

INTRODUCTION

New implant designs with improved surgical and prosthodontic options have extended the benefits of implant dentistry in patients previously excluded from therapy due to anatomical limitations or other reasons.(1) One of the disadvantages of dental implants is its expensive products. Therefore, manufacturers recognized that the high cost of implants could reduce the growth in this market.(2,3) In Egypt there is an increased patient's knowledge and demand, and thus, a wider market for implant treatment. But the most important factor that slows the progress of the dental implant market is the cost. Accordingly, some companies thought to produce the locally manufactured implants in order to reduce the costs for Egyptian patients. In an attempt to encourage the local industry and reach to the international implant level together with reducing the cost for patients, continued evaluation of the local implants as compared to the international implants is necessary to determine the difficulties that face the dentists, patients and local manufactures.

AIM OF THE WORK:

Our objective is to explore, evaluate, guide the Egyptian implant manufacturing toward better performance, and to discover the positives, and negatives of each system, hoping to reach the international market in the future.

- Accordingly the present study was designed to accomplish the following:

1- Clinical evaluation of the local implant system as compared to the international implant utilizing an objective and subjective methods.
2- Radiographical evaluation of osseointegration around dental implant systems.
3- Laboratory study to evaluate the sterilization and the chemical consistency of the implant materials used.

MATERIAL AND METHODS:

Patient selection:

In the present study, eighteen, completely edentulous cases were selected from the outpatient clinic, Faculty of Dentistry, Alexandria University and Alexandria Dental Research Center to receive mandibular implant overdenture retained by two implants in the canine area. Six implants have also been used in the laboratory evaluation of dental implant material. All patients were non smokers and free from systemic diseases. They had enough bone height and width in the area in which the implants to be placed, and sufficient inter arch space.

Preoperative patient evaluation:

- Medical and dental history, intraoral examination, panoramic radiograph and study casts were made.

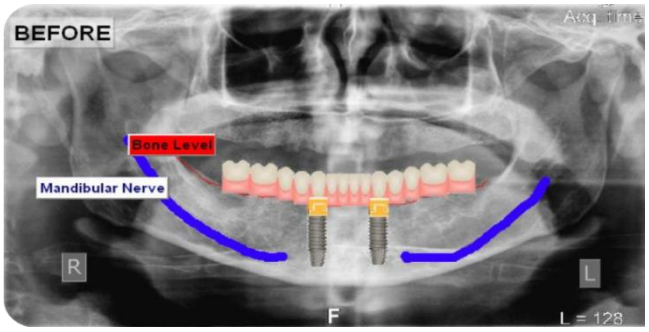


Figure: 1: The treatment plan was performed using a software program

- The treatment plan was performed using a software program.
- Radiographic clear stent was constructed using a plastic vacuum formed machine with embedded metallic marking balls at each implant site.
- For each patient a complete denture was constructed with conventional method.

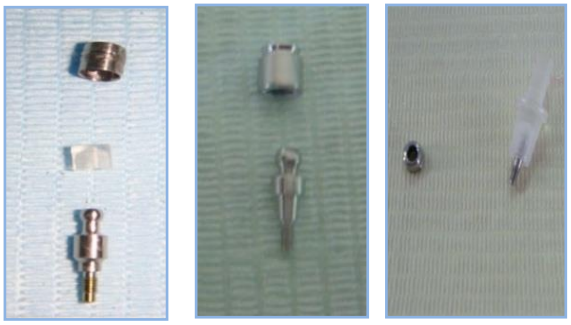
All patients were divided into three groups (A, B, C). Six patients for every group

Figure: 2: Radiographic stent

- *Group A*[*]: (control group) patients received two reputable international, titanium, threaded endosseous implants. (Prodigy)
- *Group B*[**]: patients received two locally manufactured, titanium, threaded endosseous implants (EDIM-II)
- *Group c*[***]: patients received two locally manufactured, titanium, threaded endosseous implants (TuT-II)

Prodigy EDIM-II TUT-II

Figure: 3 : Implant fixtures



Prodigy EDIM-II TUT-II

Figure: 4: Ball & socket abutments

Surgical phase:

- In each case, two stage procedure was carried out according to original Branemark protocol.
- After taking x-ray and determining the location of the implants, the metallic balls were removed and the stent was perforated in the planned implant areas to modify a radiographic stent to be used as a surgical stent.
- In **first stage surgery** the two fixtures were inserted parallel to each other, in proper angulation and both to the proper depth, then the mucoperiosteal flap was repositioned and sutured. The postoperative instructions were given to the patient.

[*] American type implant system (Biohorizon).

[**] Modern Techniques & Materials Engineering Center (MTM), Egypt.

[***] ECDI (Egyptian co. for dental implants).

- The implants were unloaded for about three months after implant surgery.
- Then **second-stage surgery** was performed using punch technique.

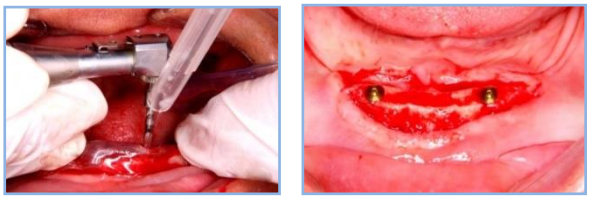


Figure 5: Insertion of two fixtures in first surgical stage surgery

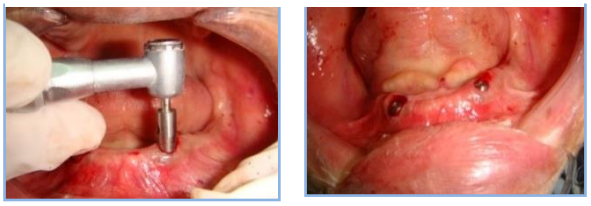


Figure 6: Punch technique

Prosthetic phase:

- Healing abutments were screwed to fixtures
- Wide holes were drilled in the denture-fitting surface opposite to the healing abutments and relined by soft liner.
- After two weeks, the healing abutments were removed and replaced by the ball abutments.
- The resilient metal housing was placed on the abutment.
- The denture was seated in the patient's mouth to determine if further relief was necessary opposite the abutments to accommodate the housings without contact between them and the denture.
- The resilient metal housing was secured to the fitting surface of the denture using autopolymerizing acrylic resin [pick up technique]

Figure 7: the resilient metal housing was secured to the fitting surface of the denture

I) Clinical Evaluation:

Clinical assessment, using the periodontal parameters including modified plaque index, modified gingival index, modified bleeding index, probing depth and mobility were used for evaluation at final prosthesis insertion, after six and twelve months of loading in all groups.

II) Radiographic Evaluation:

All groups were examined radiographically using standardized direct radiography (RVG) (vistaray, CCD system), with (XCP) extension cone paralleling device for parallel cone technique, immediately after insertion of prosthesis, six months and twelve months later to evaluate the marginal bone height and bone density.

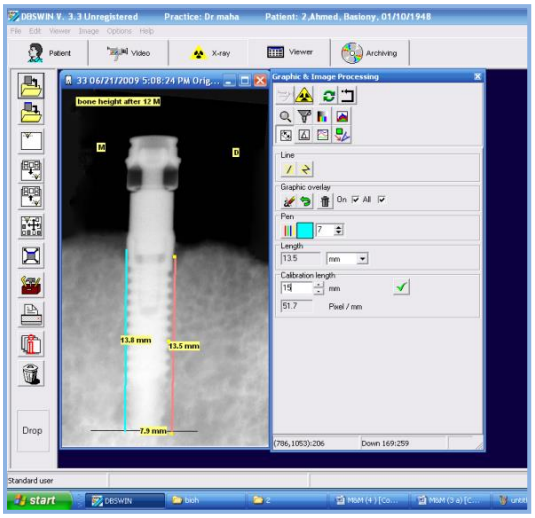


Figure 8: Bone height changes

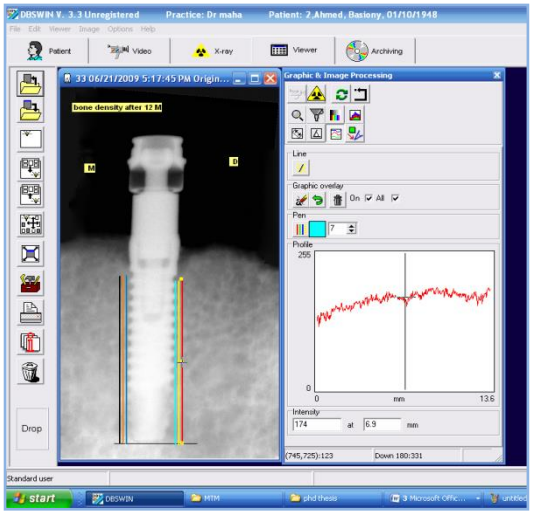


Figure 9: Bone density measurements

III) Prosthetic Evaluation:

The following prosthetic parameters were considered: Denture adjustment, ball housing complications, replacement of resilient components, abutment complications, relining or repair of

overdenture, instability or inadequate retention of the dentures and other complications like implant loss, or acrylic resin fracture.

IV) Surgical kit Evaluation:

For each implant type, the surgical kit has been evaluated to verify simplicity of the system, way of presentation, color coding, ease to use, education, and cost in relation to value.

***V)* Laboratory Evaluation of Implant Material:**

The following tests have been performed:

- *Chemical analysis of dental implant:*

Scanning electron microscopy-energy dispersive spectroscopy detection method (SEM*-EDS**) was used to determine the chemical composition of implant metal in percentage and to map the features of titanium contamination (during fabrication or storage).

The samples of implants were very carefully handled in order to prevent contamination during manipulation. Implants were analyzed as received without any preparation procedure. The analysis was performed on the flat area of apex of implants, and the elements were detected through **Link Isis software program**.

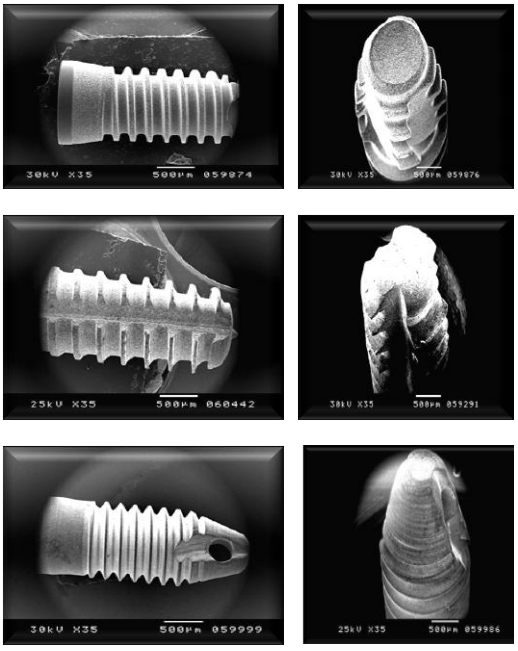


Figure 10: Scanning electron microscopy-energy dispersive spectroscopy detection method

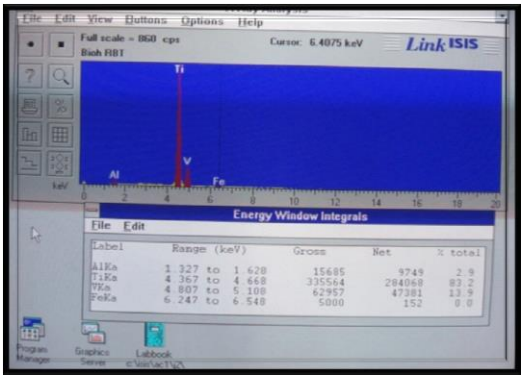


Figure: 11: The analysis was performed through Link Isis software program.

- *Microbiological analysis of implant fixture:*

This was carried out by injecting transport media in each implant bottle using sterilized plastic disposable syringe to avoid any contamination. After 10 minutes, two samples from each group were withdrawn from its bottle and cultured on two separate blood agar plates, three plates were inserted in the incubator for 48 hours at 37°C to allow the growth of micro-organisms and to test the presence of aerobic bacteria. The other three blood agar plates were inserted in the jar containing gas generating kit before placing it in the incubator for 48 hours at 37°C to test the presence of anaerobic bacteria. This test was done to check the sterilization and sealing of implant package.

It was divided into two grades:

0 = Sterile (no bacterial colonization on blood agar)

1 = Not sterile (bacterial colonization on blood agar)

RESULTS:

There were four early implant failures of locally manufactured implants during the healing period. Two implants from group (B), two from group (C). One case from each group was replaced by another implant while the other two cases refused to continue and were excluded from the study. However, no implant failure had occurred after overdenture insertion in the three groups.

I) Clinical evaluation: Clinical results as regard the peri-implant parameters showed no significant difference between the three implant system groups at the end of the study.

II) Radiographic results revealed a reduction in the bone height level in all groups without significant difference. Although there was a significant difference during the intervals (from loading time to six months) and (six months-twelve months) in each group.

* JEOL- JSM-5300. Japan – Electrooptics Ltd

** Oxford instruments, England

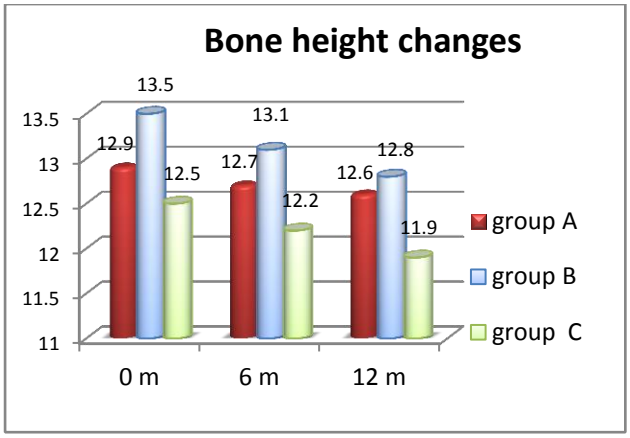


Figure: 12: Shows the mean of bone height changes around the implants of three groups immediately after loading, 6 m and 12 M

There was a significant increase of bone density in group (A) than the other two groups after one year of denture loading, in addition to a significant increase in bone density at all intervals of three groups.

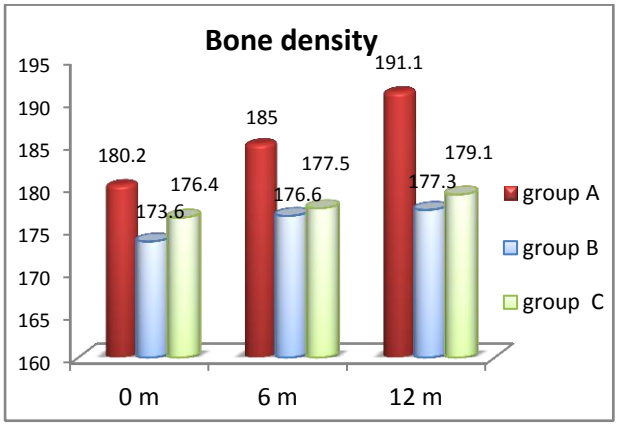


Figure 13: Shows the mean of bone density around the implants of three groups immediately after loading, 6m and 12m

III) Prosthetic Evaluation:

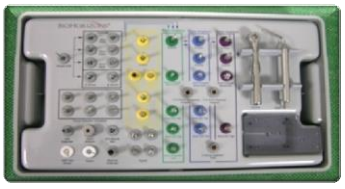
Although the Biohorizon implant system had less prosthetic complications, there was no significant difference between the three groups.

	(A) Biohorizon		(B) MTM		(C) TUT	
	No.	%	No.	%	No.	%
Denture adjustment	1	16.7	2	33.3	2	33.3
Ball housing complications	1	16.7	0	0.0	0	0.0
Replacement of resilient components	0	0.0	1	16.7	0	0.0
loose Abutment	1	16.7	2	33.3	2	33.3
fractured abutment	0	0.0	1	16.7	0	0.0
Early implant failure	0	0.0	2	33.3	2	33.3
Late implant failure	0	0.0	0	0.0	0	0.0

Table 1: Comparison between the different studied groups according to prosthetic evaluation

IV) Surgical kit Evaluation:

The surgical kit evaluation revealed that the Biohorizon surgical kit was the best one as it is well designed, labeled, color coded, and easily identified.



Biohorizon surgical kit

MTM surgical kit

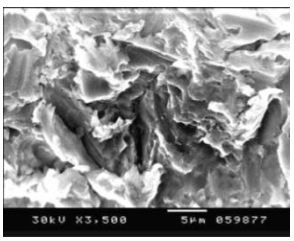
TUT surgical kit

Figure 14: Surgical kits of three implant system

V) Laboratory Evaluation of Implant Material:

- *Chemical analysis of dental implant:*

The chemical analysis of implant fixtures was performed by SEM-EDS, which revealed titanium, aluminum and vanadium (Ti, Al, V) in the Biohorizon as well as in both Egyptian implants MTM and TUT which mean that all fixtures are made from titanium alloy (grade V). The analysis showed also presence of small amount traces of silicon (Si) in (group B) and iron (Fe) in (group B, C) which were not present in the group (A).



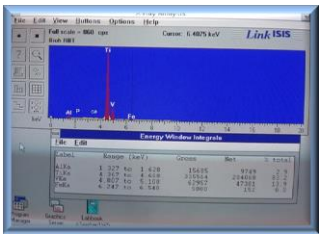


Figure 15: *Chemical analysis of implant fixtures by SEM-EDS*

- *Microbiological analysis of implant fixture:*

The microbiological analysis (sterilization test) of implant fixtures revealed that samples of the three groups were free from any bacterial contamination.

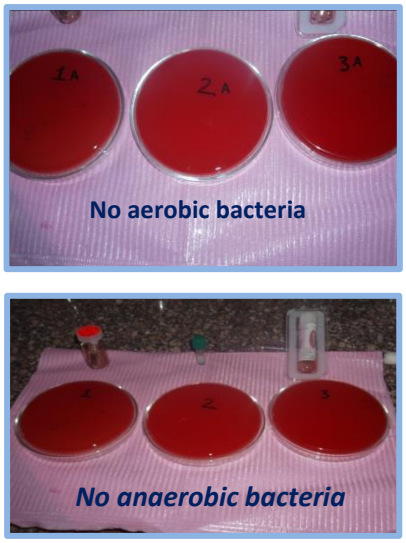


Figure 16: Microbiological analysis of implant fixture

DISCUSSION:

Biohorizon (prodigy) international implant system, selected in this study, is a two stage system, a screw type, bone based implant system which provides high primary implant stability and has reported a high success rate. In addition, its prosthetic components are easy to use and require little maintenance.[4,5] The surface characteristics of implants used in our study was reasonable blasted texture (RBT) which is processed by roughening the surface with tri-calcium phosphate blast media for increasing the biological fixation and maximizing implant-to-bone contact.[5] **Piattelli** et al, [6] studied the bone response to machined and resorbable blast material (RBM) titanium implants in an experimental study on rabbits. They proved that RBM implant surface exhibited higher bone-to implant contact.

In the present study "Biohorizon" implant system was used and its effect was evaluated versus the only two locally manufactured Egyptian implant systems in the market (MTM and TUT). The choice of EDIM-II representing MTM system, and TUT- II representing TUT group was based on being both screw types, two stage systems and their surfaces are sand blasted and etched which increased the implant surface roughness promoting the osseointegration. Nordin et al,[7] showed that implants with sandblasted and acid etched surfaces had high bone to implant contact.

The **results of our study** revealed that most of the implants used showed no clinical mobility after loading throughout the study. This indicates that osseointegration was achieved and maintained during the evaluation period.[8] On the other hand, four implants failed in four cases during the healing period prior to insertion of overdenture. Two implants from group (B) and two from group (C). One case from each group was replaced by another implant while the other two cases refused to continue and were excluded from the study. The exact cause of the failures was unknown. Implants fail for a variety of reasons. Some studies have related failures to biological factors, while others attribute dental implant failure to biomechanical factors, bilateral factors, or implant surface treatments and characteristics. [9,10,11]

The **bone height changes** in group (A) were less than the other two groups which means that group (A) has less bone resorption. The mean vertical bone loss at twelve months was 0.2 mm for group (A), and 0.6 mm for group (B and C). There was no significant difference between the three groups during the follow- up period, although there was a significant difference within each group throughout the study period. The reduction of the bone height level during the first year of functioning might be related to healing and reorganization following trauma to the bone and periosteum as a result of implant surgery, this remodeling and adaptation of bone occurred to withstand functional forces.[12]

The results of our study showed a significant increase in **bone density** for all groups during follow up intervals. Moreover, there was a significant difference in bone density between group (A) and group (B) and between group (A) and group (C) at the end of the year, whereas there was no significant difference between group (B) and (C).

The increase in bone density observed in the present study may be attributed to several factors; one of which is the surface treatment of implants, which is in agreement with Taba Júnior et al,[13] who found that the soluble blasting media-treated surface added roughness to the implant leading to numerically high bone density.

Bone density could also be related to the shape of threads of dental implants used in the present study. **Steigenga e**t al,[14] showed that the square thread design implants had significantly more bone-to-implant contact (BIC) and greater reverse torque measurements compared to the V-shaped and reverse buttress thread designs. In our study, group (A) (Biohorizon) had square threads while group (B) has modified buttress threads and group (C) has V-shaped threads. This is could also explain the difference in bone density between the group A and group (B and C).

In the **prosthetic evaluation** there was no significant difference between the three groups. However, the most common complications were denture adjustment and tightening of loose abutment

which account 16.7% of group A (one case), 33.3% of group B (2 cases) and 33.3% of group C (2 cases). This is in agreement with Chaffee et al[15] who suggested that more than half of maintenance visits, were for sore spot/ulceration adjustment or ball housing tightening in mandibular implant-supported overdentures with ball attachments.

One case of group (B) had lost the retention of the denture after some time. In addition, one ball abutment of group (B) had fractured at screw part twelve months after loading. This was attributed to loss of adaptability of the resilient part of the attachment. Some of the attachment loosening, and ball screw loosening might be explained by normal function, including patient insertion and removal of the prostheses and repeated the chewing cycle. Therefore, it seems to be important to make controls for these complication risks at regular intervals. This complication could be largely prevented by attention to occlusal contacts and adequate tightening of the ball abutment. [16]

It was found that the **surgical kit** of the Biohorizon implant system was the best, in comparison to both types of Egyptian locally manufactured surgical kits because of its well organized design, all system components had a diameter specific color code. All drills were sharp, labeled with highly visible dark marks and grooves. There were depth drills, width drills and crestal bone drill. All these advantages could not be found in other two Egyptian implant systems. It was difficult to clearly view the drilling lines in locally manufactured implants, and this might adversely affect the formation of the holes during drilling. On the other hand, Biohorizon system was much more expensive than the other two types.

In this research the **chemical analysis of implant fixtures** was performed by (SEM-EDS) which revealed titanium, aluminum and vanadium in the Biohorizon as well as in both Egyptian implants MTM and TUT which mean that all fixtures are made from titanium alloy. Few additional elements were detected such as calcium and phosphorus (Ca & P) in the group (A), it could be from the biocompatible calcium phosphate which used to blast the surface. The analysis showed also presence of small amount traces of silicon (Si) in (group B) and iron (Fe) in (group B, C) which are not present in group (A). This is in agreement with some authors [17,18,19] who have reported that the majority of the elemental contamination are the organic carbon and trace amounts of N, Ca, P, Cl, Na and Si. In the meantime the early loss of four implants, two in each group B and C, could be supported by Esposito et al,[20] who suggested that some early implant failures may be caused by the presence of contaminations on the implant surface.

The **microbiological analysis** of implant fixture revealed that samples of the three groups were free from any bacterial contamination; this means that the method of sterilization used by the manufacturers was proven effective and all implant systems were presented in a sterile, well sealed package. Our results were in agreement with Costa et al[21] who analyzed the effectiveness of dental implant sterilization by means of microbial analysis on sixty implants from Neodent (Brazil), 3i implant and Nobel Biocare dental implant systems and proved that there was no signs of bacterial growth; therefore the implants were effectively sterilized and the method of sterilization used by the manufacturers was proven effective during their study.

CONCLUSION:

- According to our results it is reasonable to say that locally manufactured Egyptian implants reached a satisfactory production standard when compared to Biohorizon ones.
- Locally manufactured Egyptian implants could be accessible to many patients who seek low cost dental implants and could not pay for international types of dental implants due to their high cost.
- The Egyptian manufacturers should overcome the problems pointed in our study and consider our recommendation to improve their products.

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