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Does A Sealed Bracket Kit Give Sterility Check???

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Abstract:
Introduction*: Orthodontic brackets are classified as semicritical instruments. However, in orthodontic clinical practice, the use of brackets directly from non-sterile manufacturer's packages is still a routine. In this scenario, it becomes extremely important to assess the potential contamination of these materials so as to determine sterilization protocols and maintain the health of patients and dental practitioners.*
Objective*: To evaluate the microbial contamination of orthodontic brackets as received from the manufacturer using microbiological tests. (An in vitro study)*
Materials and Methods*: The sample comprised 25 brackets of five different commercially available brands, used directly from the manufacturer's packaging, divided into 5 groups (n =05 brackets each). Materials were tested under aseptic conditions to detect bacterial growth using microbiological tests and analyze types of bacteria present by preparing slides using gram staining protocol.*
Results*: In four of five groups the brackets showed microbial contamination: group A, 3M Unitek metallic brackets, group B, TP Orthodontics metallic brackets, group D Forestadent self ligating metallic brackets and group E,3M Unitek ceramic brackets. Microbiological analysis showed presence of endospore forming bacilli. Group C, OrthoOrganisers metallic brackets showed no contamination.*
Conclusion*: Brackets of three brands (TP Orthodontics, 3M Unitek and Forestadent) were found to be contaminated by bacteria in the original packages supplied by the manufacturers, which suggests a risk for patient contamination. These data suggest that the manufacturers of these materials should improve the quality control of the packaging used, including sterilization, for the security of patient health.*

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I. Introduction

The placement of orthodontic appliances creates a favorable environment for the accumulation of a microbiota and food residues.[1]The development of plaque has been associated with several environmental and individual factors including diet composition, oral hygiene, fluoride exposure, the quality of saliva, the composition of the oral microflora, and immune factors. Fixed or removable orthodontic appliances also impeded the maintenance of oral hygiene, resulting in the plaque accumulation.[2]

The oral microbiota in the human oral cavity contains a number of different habitats and at least 400 to 700 different types of bacteria. This microbiota host a complex and dynamic microbial community that is responsible for two major and highly prevalent infectious diseases: caries and periodontal disease.[4]

When changes occur in the oral cavity, the microbiota also change, causing a loss of balance and increasing the possibility of disease development.[5]Orthodontic treatment, via the use of fixed or removable appliances, causes specific alterations in the oral cavity,[6] including pH reduction, increased accumulation of dental biofilm,[7] and increased levels of microorganisms in saliva and biofilm.[8,9] As a result, diseases can be transmitted through direct contact with contaminated instruments or materials, either when used straight from the manufacturer's packaging or when used in more than one patient without proper disinfection or sterilization.[10] In orthodontics, several products are available for disinfecting and sterilizing instruments (eg, orthodontic pliers), but data on the microbial contamination of orthodontic brackets as supplied by the manufacturers are lacking in the literature. The brackets that are attached to patients' teeth are usually removed from the manufacturer's original container and transferred straight to the patient's mouth, where they stay for an average of 2 to 3 years. International regulatory agencies have recommended the use of the Spaulding classification system for inanimate objects to evaluate their potential risk of disease transmission and infection.[12] This classification system is used by different centers of epidemiologists, microbiologists, and professional medical organizations aiming to determine the degree of disinfection or sterilization required for various medical devices and classifies objects as critical, semicritical, or noncritical. [3]

According to this classification, orthodontic materials, including brackets, are considered semicritical because of the associated risk of infection (direct contact with the oral mucosa), and should therefore be

sterilized before use. Semicritical objects are those that have contact with mucous membranes only, preventing the invasion of subepithelial tissues, and should be sterilized.[12] Purmal et al.[4] evaluated four different orthodontic buccal tubes used straight from the manufacturer's packaging and found aerobic bacterial contamination. The microorganisms isolated from the samples were Micrococcus luteus, Acinetobacter calcoaceticus, and Staphylococcus haemolyticus, microorganisms with a contamination potential that can pose risks to patients' health. Those authors recommended that the materials should be sterilized before use.[4]

Based on these findings and the absence of studies, and taking into consideration the patient safety risks involved and the fact that materials that will be used in the oral cavity must be free of contamination,[12]the objective of this study was to test the null hypothesis that orthodontic brackets as supplied by manufacturers do not present microbial contamination. To that end, microbiological test was used to detect the presence of bacterial growth, analyze the types of bacteria present.

II. Materials And Methods

The sample comprised 25 brackets of different lots of five commercially available brands, divided into 5 groups of 5 pieces each, used straight from the manufacturer's package.(Fig 1)

Group	Bracket	Brand	Manufacturing package
1	Metallic	3M Unitek	Full case
2	Metallic	TP Orthodontics	Full case
3	Metallic	Ortho Organiser	Full case
4	Metallic	Forestadent	Full case
5	Ceramic	3M Unitek	Full case
Total	25 brackets		

The samples were subjected to qualitative analysis using a microbiological test to determine the presence of bacterial growth as well as biochemical tests to determine the morphology of the microorganisms and to assess the types of bacteria possibly present.

Microbiological Tests

Bacterial growth: For microbiological analysis, 3.7 g of BHI (Fig 2) broth (Himedium, Mumbai, India) were prepared and diluted in 100 mL of distilled water. The solution was heated until dissolving and distributed into 25 test tubes (2 mL/tube). (Fig 3)

Subsequently, the tubes were autoclaved for sterilization at 121 degree C and 15 lbs pressure for 15 minutes. At this point, orthodontic brackets were distributed into the test tubes containing the sterilized BHI broth under aseptic condition and placed in an incubator for 48 hours at 37 degree C. (Fig 4, 5, 6) Analysis of bacterial growth was based on changes in the color of the medium in each tube: tubes showing darkening or turbidity of the BHI medium were considered positive for bacterial growth and further investigated.(Fig 7-12)

Biochemical analysis: Tubes showing growth of colonies were fixed in glass slides. [17] Slides were evaluated using an optical microscope (Leica, CME model, Wetzlar, Germany) to determine the morphology of the microorganisms and to assess the types of bacteria possibly present.(Fig 13)

III. Results

According to the results of the microbiological tests, none of the samples in control group showed darkening or turbidity of the BHI medium, confirming absence of bacterial growth. This confirms the effectiveness of the sterilization method used for the BHI medium.

Of all groups evaluated only one group i.e. group C showed no contamination, and it occurred in 100% of the samples. In group D, 60% of samples showed no contamination. On visual identification, group A showed turbidity with bacterial pellicle formation. Group B and group E showed bacterial pellicle formation with clear medium. After visual identification of bacterial growth as per darkening of the BHI medium, groups A, B, D and E were subjected to microbiological analysis, which revealed the presence of colonies of endospore forming bacilli.(Fig 14)

IV. Discussion

Various studies have been done to determine the effects of fixed orthodontic appliances on microbial flora and periodontal status. In clinical practice sterilization plays crucial role to eliminate the factor of introducing the loci of infection in the patient's mouth. Various sterilization protocols have been formulated to follow to avoid infection. As we know orthodontists directly use the brackets from the bracket kit given by manufacturer and bond it in the patient's mouth. No sterilization protocol has been practiced. Hence aim of this

study was to determine whether the orthodontic brackets in the sealed kit are sterilized enough to use directly in the patient's mouth.

Infection by microorganisms is a concern for health care professionals in general and for dental practitioners in particular, and the dental literature has long pointed to the need to sterilize or disinfect any material before its use in the oral cavity. However, in orthodontic clinical practice, the use of bands and brackets directly from non-sterile manufacturer's packages is still a routine. In this scenario, it becomes extremely important to assess the potential contamination of these materials so as to determine sterilization protocols and maintain the health of patients and dental practitioners working in this field.[3]

In the present study, bacterial contamination was confirmed in orthodontic brackets supplied by three of the manufacturers assessed, namely group A, TP Orthodontics (Europe), and group B, E 3M Unitek and group D Forestadent Similarly, Purmal et al.[4] also reported biological contamination of the orthodontic buccal tubes evaluated in their study. Those authors suggested that the presence of the bacteria could result from unhygienic practices during material manufacturing and packaging, justifying the results in packages and in full case and replacement brackets.

According to Anhoury et al.,[6] in a healthy oral environment, the interplay between microorganisms and the host is complex and balanced. However, when orthodontic brackets and bands are placed in the oral cavity, they can induce such changes as a decrease in pH and biofilm accumulation, especially when the materials used have not been previously sterilized.[6] The relationship between changes in the oral microbiota and the use of orthodontic materials has been confirmed by Naranjo et al.,[7] who found alterations in subgingival microbiota after the placement of orthodontic bands.

In our study, bacterial contamination of groups A,B,D and E was suggested by biochemical tests and confirmed by microscopic examination. Looking at previous studies, Purmal et al.[4] found M luteus, S haemolyticus, and A calcoaceticus,[4] whereas Hong et al.[8] found an increase in Streptococcus mutans in the saliva and biofilm after the placement or orthodontic brackets.[8]

With regard to the pathogenicity of microorganisms, Andrucioli et al.[3] had already underscored that high levels of oral microorganisms increase the risk not only of caries and periodontal disease but also of systematic complications.[15] According to Levinson and Jawetz[3] S epidermidis may cause endocarditis, a rare but possible complication of dental treatment that will only develop in the presence of bacteremia.[14]McLaughlin et al.[16] and Erverdi et al.[16] have also suggested an association between certain orthodontic procedures, for example, orthodontic banding, and bacteremia.[16]

About 75% of bacterial infections caused by coagulase-negative Staphylococcus have S epidermidis as the causative agents[3,16] These bacteria rarely cause suppuration, but they can infect orthopedic and cardiovascular prostheses and cause diseases in immunosuppressed persons. Also it is observed that as bacilli grow faster than cocci their colonies can mask the coccal growth.[17]There is a possibility of this in our study too.

About the S aureus found in brackets in study by Gerzson et al[3], their pathogenic capacity is in the combined effect of extracellular factors and toxins, together with their invasive properties. Dissemination of S aureus can cause endocarditis, osteomyelitis, meningitis, or lung infection.[3] According to Oliveira et al.,[3] the presence of these respiratory pathogens in the biofilm can serve as a reservoir for microorganisms associated with nosocomial pneumonia.

Finally, considering that not all materials from manufacturers are free of contamination on the packaging, the null hypothesis was rejected. This suggests a concern for the health of patients and the need for better control of contamination in packages of brackets.

CLINICAL IMPLICATION

Manufacturers (TP Orthodontics, 3M Unitek, Forestadent) should follow strict protocol for sterilization of the orthodontic brackets, and clinicians should not rely on the seal of the bracket kit as a sterility check.

V. Conclusion

As three out of five brands in this study showed contamination by bacteria in the original packages supplied by manufacturers, these data suggest that-

1] Manufacturers of these materials should improve the quality control of packaging used

2] Clinicians should use a method of disinfection or sterilization before their use in the orthodontic clinic for security of patient health.

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Figure 1 Brain Heart Infusion Broth

Figure 2 Preparation of test tubes for each group (5 groups with control) with sterile medium

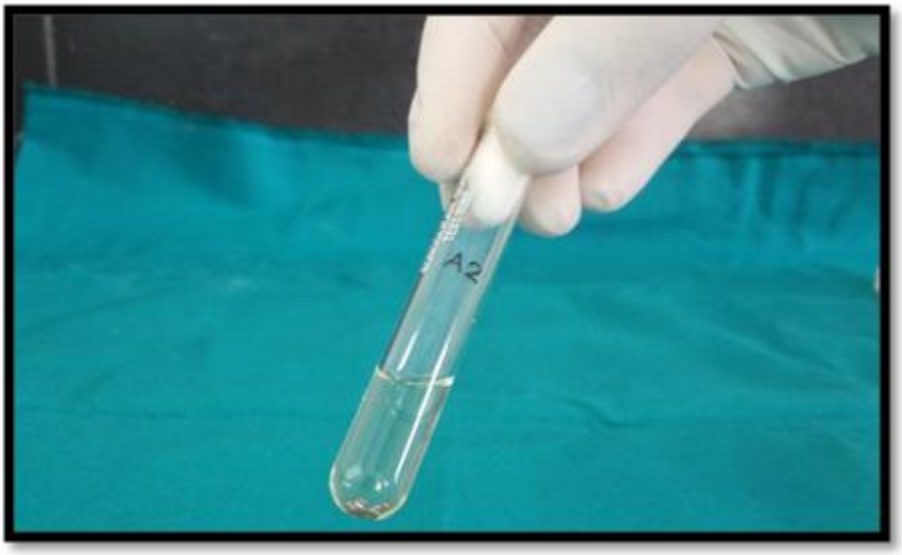

Figure 3 Placement of bracket inside sterile medium and labeling

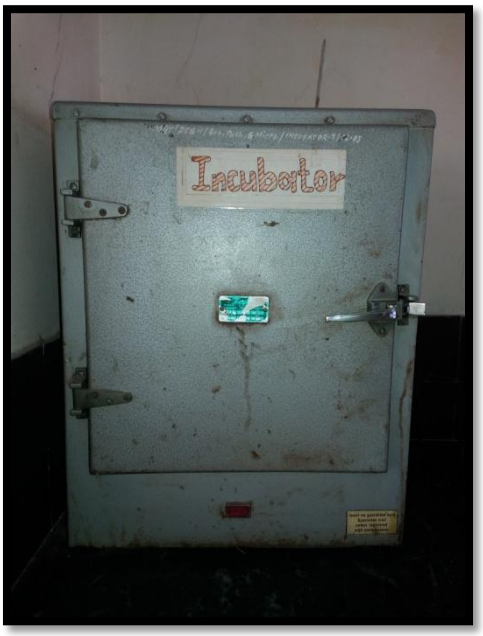

Figure 4 Incubator

Figure 5 Incubation of test tubes with brackets at 37 degree C for 48 hrs

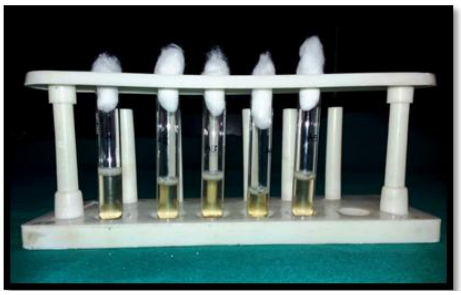

Figure 7 Group A After incubation

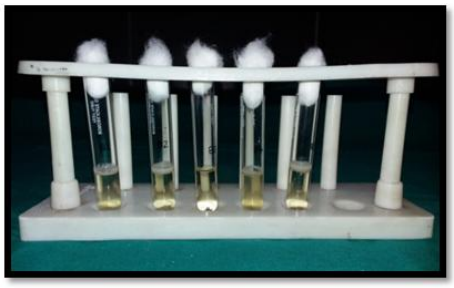

Figure 8 Group B After Incubation

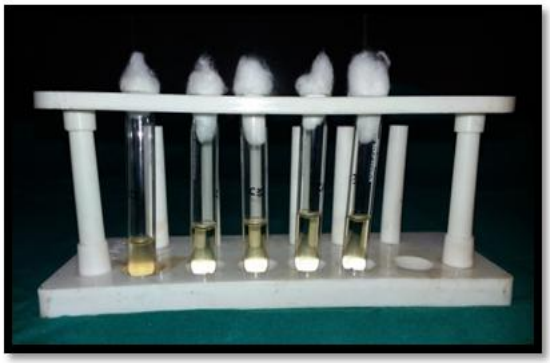

Figure 11 Group E after incubation

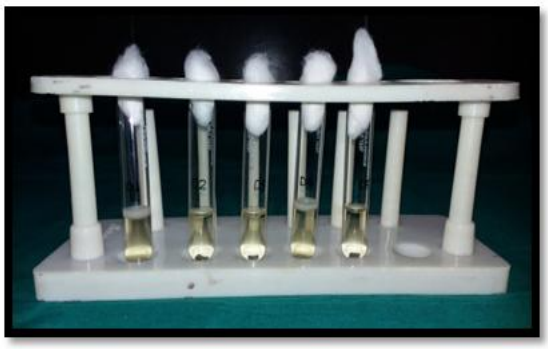

Figure 10 Group D After Incubation

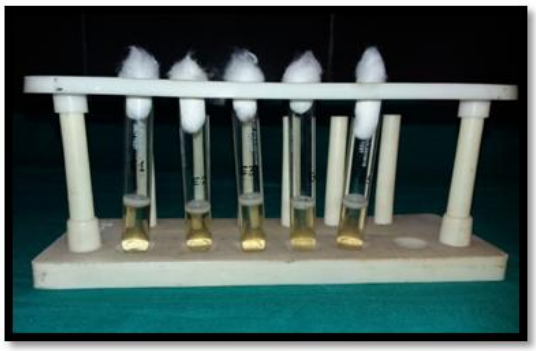

Figure 9 Group C After Incubation

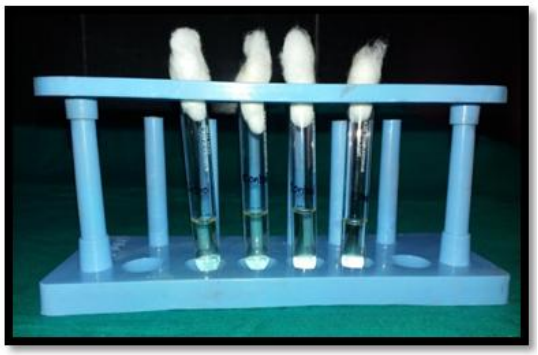

Figure 12 Control After Incubation

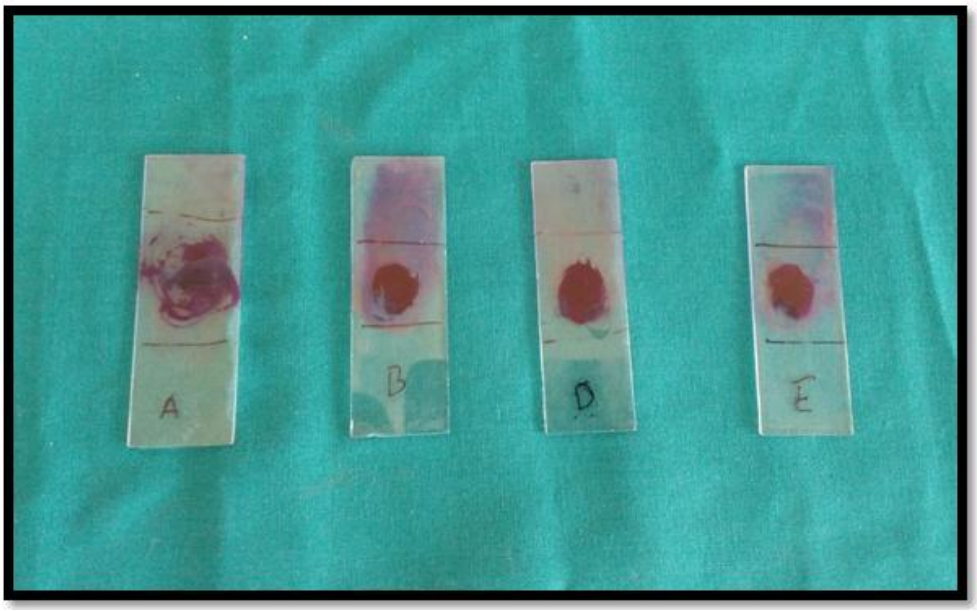

Figure 13 Slide Preparation Of Groups Showing Bacterial Growth

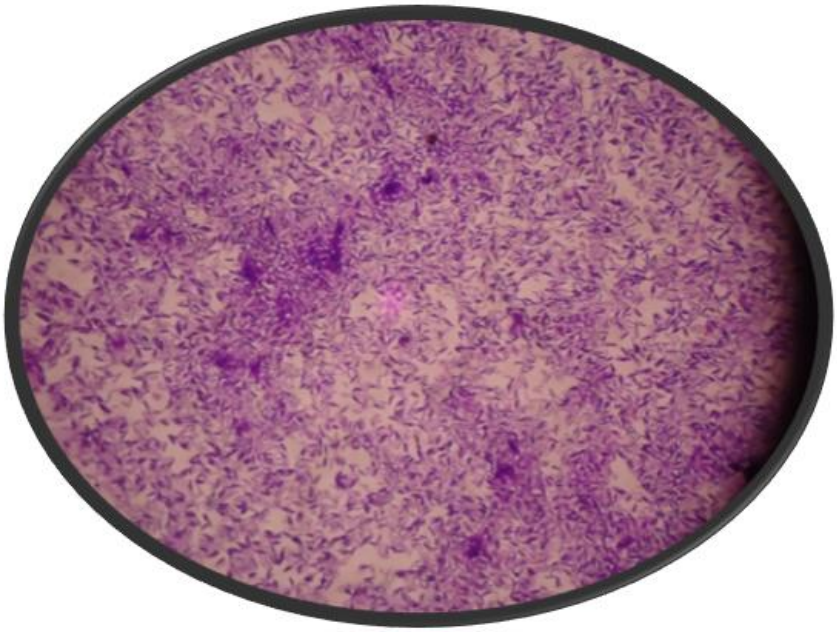

Figure 14 Microscopic View Of Endospore Forming Bacilli

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