	TEST REPORT	Report No.	REID-21-06-15-N137
		Date of Issue	June 15, 2021
	Bacterial penetration into the connection part between COWELL® Fixture and Abutment: an *in vitro* test		

1. Specimen

1.1. Fixture: INNO Sub. Fixtures with the SLA-SH™ treated on their surfaces (5ea).
1.2. Abutment: Sub. Cemented Abutments with TiN coated on their posts (5ea).

2. Classification

2.1. UMDN: 16744 Prostheses, Dental, Implantable.
2.2. MFDS: C20030.01[3]: Implant, Endosseous, Fixture.
C20040.01[2]: Implant, Endosseous, Superstructure.

3. Model Numbers

3.1. INNO Sub. Fixtures: ST4010SM-21E100211A81 (#1), (Fig. 1).
ST4010SM-21E100211A82 (#2), (Fig. 2).
ST4010SM-21E100211A83 (#3), (Fig. 3).
ST4010SM-21E100211A84 (#4), (Fig. 4).
ST4010SM-21E100211A85 (#5), (Fig. 5).

Fig. 1. #1 **Fig. 2.** #2 **Fig. 3.** #3 **Fig. 4.** #4 **Fig. 5.** #5

3.2. Sub. Cemented Abutments: 2SCH4547-21B050100A26 (#6), (Fig. 6).
2SCH4547-21B050100A27 (#7), (Fig. 7).
2SCH4547-21B050100A28 (#8), (Fig. 8).
2SCH4547-21B050100A29 (#9), (Fig. 9).
2SCH4547-21B050100A30 (#10), (Fig. 10).

Fig. 6. #6 **Fig. 7.** #7 **Fig. 8.** #8 **Fig. 9.** #9 **Fig. 10.** #10

4. Manufacturer: Cowellmedi Co., Ltd.

48, Hakgam-daero 221 beon-gil, Sasang-gu, Busan, 46986 Republic of Korea
Tel. +82 (0)51 314 2028
Telefax. +82 (0)51 314 2026

5. Place of the Test: REID (Research & Education in Implant Dentistry).

6th Floor, 42, Seochojungang-ro, Seocho-gu, Seoul, 06643 Republic of Korea
Tel. +82 (0)2 3453 5085
Telefax. +82 (0)2 3453 5086
www.cowellmedi.com/doctor/eng/page/reid.jsp

6. Period of the Test: May 25, 2021 to June 1, 2021.

7. Purpose: To test whether such microorganisms as bacteria may penetrate into the connection part between the fixture and abutment when they are precisely connected and tightened.

8. Criteria: There is no bacterial penetration between the connection part of the fixture and the abutment since the turbidity of the culture medium in the test tube does not differ during the incubation period compared to the negative control (Fig. 11.).

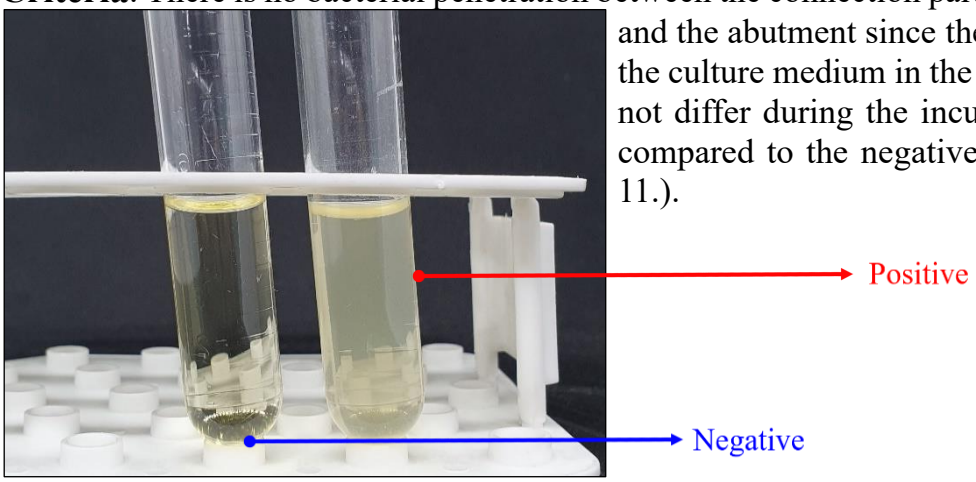

Fig. 11. Different turbidity between the positive and negative control.

9. Equipment used for the test

9.1. Shaking incubator (Fig. 12).
9.2. Model number: IS-971R.

Fig. 12. Shaking incubator

10. Methods: The following procedures were carried out on a clean bench.

10.1. An abutment was connected to a fixture (Fig. 13).
10.2. The culture medium was injected into the abutment screw hole (Fig. 14).
10.3. The abutment screw was tightened with a force of 30Ncm (Fig. 15).
10.4. The abutment screw hole was sealed using a flow resin (Fig. 16).
10.5. All the surfaces of the fixture and abutment were cleaned using alcohol-soaked gauze and cotton swabs (Fig. 17).
10.6. All the other fixtures and abutments were treated in the same methods as above.
10.7. After immersing all the specimina in the test tubes, they were incubated at 37°C, 200rpm for 168 hours in the shanking incubator (Fig. 18).

Fig. 13.

Fig. 14.

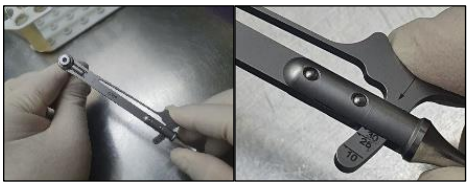

Fig. 15.

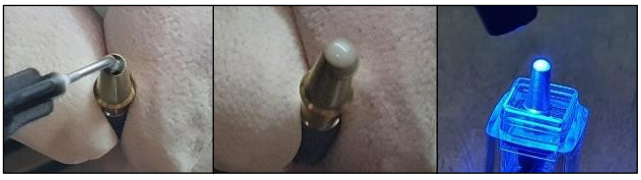

Fig. 16.

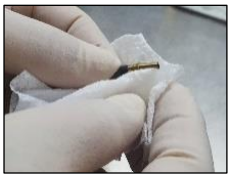

Fig. 17.

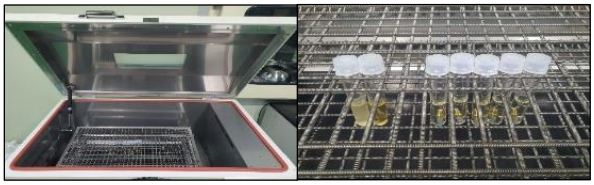

Fig. 18.

11. Results

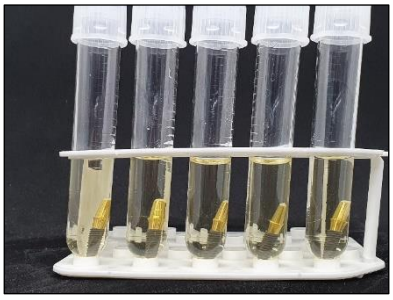

Fig. 19. For 24 hours, negative.

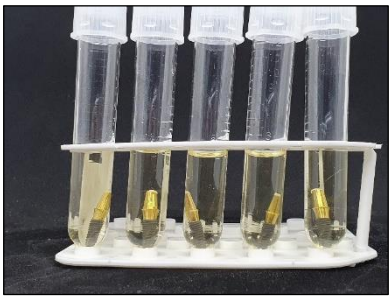

Fig. 20. For 48 hours, negative.

Fig. 21. For 72 hours, negative.

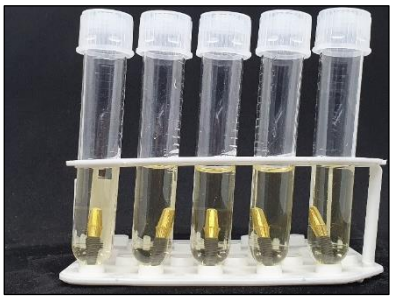

Fig. 22. For 96 hours, negative.

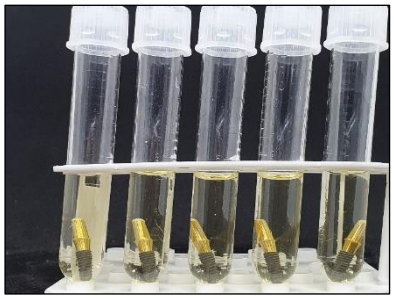

Fig. 23. For 120 hours, negative.

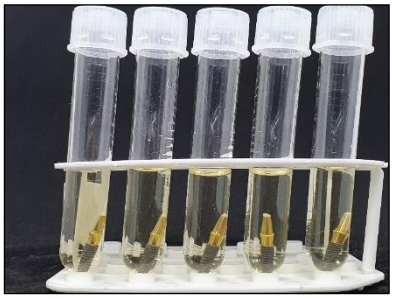

Fig. 24. For 144 hours, negative.

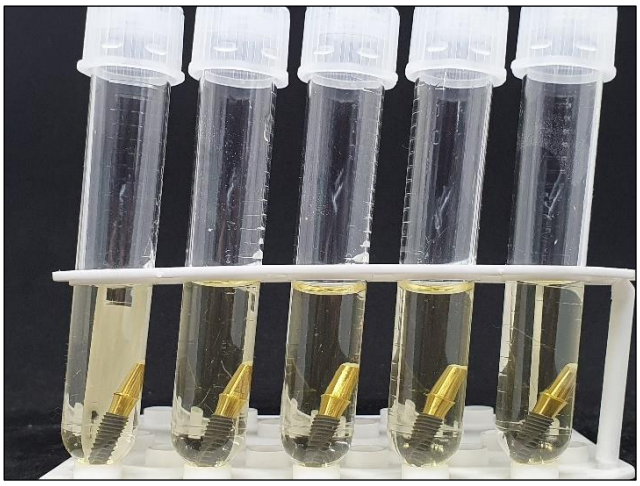

Fig. 25. For 168 hours, negative.

12. Conclusion

When the turbidity of the culture media in the test tubes was compared to the negative control, there was no difference during the incubation period, indicating that there was no bacterial penetration into the connection part between the fixture and the abutment.

In addition, it is assumed that there is no micro-gap between the connection part of the fixture and the abutment within the limitation of this test.