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FINAL STUDY REPORT

STUDY TITLE

Endodontic usage Test

SAMPLE NUMBER

PDS-64-2019-0014

PRODUCT NAME

Injectable Root Canal Bioceramic Sealer

STUDY COMPLETION DATE

June 23, 2020

MANUFACTURER NAME AND ADDRESS

Beijing C-Root Dental Medical devices Co.LTD
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SPONSOR NAME AND ADDRESS

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PERFORMING LABORATORY

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Specification

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2. The test report should not be duplicated without the approval of the test unit;
3. The copy of test report is invalid without the re-stamped official seal;
4. The test report is invalid without the signature of approver;
5. The test report is invalid if it has signs of erasure;
6. The testing results and the testing unit name in the test report should not be used for advertisement, excellence selection activity and commercial propaganda without getting agreement;
7. If there is any objection to the test report, it should be presented within 15 days from the date of receiving the test report, otherwise it is not accepted;
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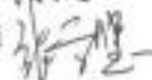
Summary

This test was performed to assess the biocompatibility of endodontic materials with the remaining apical pulp tissues (stumps) and the periapical tissues by filling the test sample of Injectable Root Canal Bioceramic Sealer into the root canal of Beagle dogs. This test was conducted based on Chinese medical industry standard YY/T 0127. 3-2014 "Biological evaluation of medical devices used in dentistry-Part 3: Endodontic usage test".

After animals are under general anesthesia, all calculus and debris are removed from the tooth surfaces, and then the surfaces of teeth were cleaned and disinfected. Pulp chamber of each required teeth was opened, the pulp was extracted, the working length of the test tooth was determined, and the root canal was prepared to 25#. Each root canal was irrigated repeatedly with 2.5% (m/m) sodium hypochlorite solution and 0.9% saline solution (m/m). The water was dried with sterile absorbent paper tips. After the root canal was disinfected, the canal was filled with Injectable Root Canal Bioceramic Sealer and guttapercha points with lateral condensation technique. The access cavity was obturated with composite resin. Macroscopic and histological observation of the teeth and supporting tissues were performed on 28 and 90 days after surgery. At the time period of 28 days, among the 10 test specimens, 8 specimens showed no inflammation; 2 specimens of periapical tissue showed mild inflammation; no specimens showed moderate inflammation and severe inflammation. Among the 5 control specimens, there were no specimens showed the inflammation response, and no specimens showed moderate inflammation and severe inflammation. At the time period of 90 days, among the 10 test specimens, 10 specimens showed no inflammation. Among the 5 control specimens, 4 specimens showed no inflammation; 1 specimens of periapical tissue showed moderate inflammation and no specimens showed severe inflammation. Chi-square test showed that there was no significant difference between the control group and the experimental group in the 28-day period ($P>0.05$) and 90-day period of this experiment ($P>0.05$).

This report replaced and abolished the Inspection Report of PDS-64-2019-0014-GGBGE issued on November 4, 2020.

Study and Supervisory Personnel: Chai Yuan 

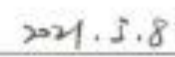
Zhang Xuehui 

Study Completion Date: June 23, 2020

Approved By:



Han Jianmin



Date Issued

Introduction

This test was performed to assess the biocompatibility of endodontic materials with the remaining apical pulp tissues (stumps) and the periapical tissues by filling the tested sample of Injectable Root Canal Bioceramic Sealer into the root canal of Beagle dogs. This test was conducted based on Chinese medical industry standard YY/T 0127, 3-2014 "*Biological evaluation of medical devices used in dentistry-Part 3: Endodontic usage test*". The test article was received on April 9, 2019. The study was began on May 9, 2019, and the observations were concluded on June 23, 2020.

Materials

1. Test article

Sample number: PDS-64-2019-0014

Test article: Injectable Root Canal Bioceramic Sealer

Type: C-Root SP

Lot number: 181201

Sample description: White paste packaged in the plastic tube, the outer package is plastic bag. The packaging is intact without damage.



Storage condition: Room temperature.

Sample disposition: Any remaining sample will be returned to the sponsor.

2. Control sample

Injectable Root Canal Sealer (iRoot SP, IBIOCERAMIX, Lot,18004SP)

3. Other materials used in this test

Guttapercha points (Liu Yuan, Shandong Dayading Medical Appliance Co., LTD);

Adhesives (Opti Bond, Kava Kerr);

Composite resin(Harmonize, Kerr).

Methods

1. Test system

Species:	Beagle Dog
Strain:	Beagle Dog
Source:	The experimental animal supplier approved by the test center.
Sex:	No special requirement.
Body weight range:	No special requirement.
Age:	One year old
Acclimation period:	15 days
Number of animals:	Four
Identification method:	Separate cage marking.

2. Justification of test system

Beagle dog has been used historically for endodontic usage test. International and national standards have recommended endodontic usage test for assessing the biocompatibility of endodontic materials.

3. Animal management

Husbandry: Conditions conformed to standard operation procedure which made according to specification of experiment animal protection and usage.

Feed: Certified commercial diet was provided daily.

Water: Tap water sterilized by autoclaving.

Contaminants: Contaminants in feed or water supplies did not have the potential to influence the outcome of this. test.

Housing: Animals were housed in groups in plastic cages. Cages were identified by a card indicating the sample number, sex, animal group code and beginning date of the study.

Environment: The room temperature and room humidity were monitored daily. The room temperature was controlled within 20 °C~25 °C. The room humidity was controlled at 30%~70%. The light cycle was controlled (12 hours light and 12 hours dark).

Facility: State Food & Drug Administration Medical Devices Quality Supervision and Testing

Center of Peking University was accredited by China National Accreditation Service for Conformity Assessment (CNAS) and conformity with ISO/IEC 17025 and *Medical device testing institutions qualification accreditation regulations (trial)* from State Food & Drug Administration.

Personnel: Associates involved were appropriately qualified and trained.

Selection: Only healthy and previously unused animals were selected.

Animal welfare: During the test, it should be careful not to cause injury, disease, and close to death of test animals. At the anatomical observation, the animals were sacrificed by excessive anesthesia.

4. Test procedure

(1) Sample Preparation

Manufacturers provided the test samples for use direct according to the instruction. Manufacturers provided the control samples for use direct according to the instruction also.

(2) Test Procedure

3% (m/m) pentobarbital sodium salt was administered to the animal to general anaesthesia by intravenous injection at a dosage of 1ml/1kg body weight. Each tooth surface was cleaned and disinfected with a 3% (v/v) hydrogen peroxide solution. Pulp chamber of each required teeth was opened and the pulp chamber was uncovered with sharp bur under aseptic conditions. The exposed pulp was cleaned with saline, and the pulp was removed from the apical hole (1.0 ± 0.5) mm with a new sterile root canal file or pulp extraction needle. The exposed pulp was debrided with saline solution 0.9% (m/m). A new sterile root canal file or a barbed broach was used to sever the pulp (1.0 ± 0.5) mm from the apical foramen. The working length of the test tooth was determined and the root canal irrigated repeatedly with 2.5% (m/m) sodium hypochlorite solution followed by sterile 0.9% (m/m) saline solution. The root canal was enlarged to 25# using progressively larger, sterile, root canal files and calibrated in length to the level at which the pulp has been severed. The dentinal chips were eliminated. Following completion of the instrumentation, the root canal was flushed with 2.5% (m/m) sodium hypochlorite solution followed by sterile 0.9% (m/m) saline solution and dried with sterile paper points.

For each time period, the test material was filled at least ten teeth at and with a suitable reference material was filled at least five teeth, on the basis of a random allocation. The root canal was filled with either the test or reference material and utilizing gutta percha to the point of pulp severance with lateral condensation technique. The access cavity was obturated with composite resin.

3. Observation

(1) The status of the animals was observed and recorded once a day after the operation. Take appropriate measures to minimize postoperative pain or pain caused by changes in eating habits, inflammation or infection.

(2) X-ray examination

Animals were anesthetized with appropriate anesthetics 28d and 90d after the surgery, and X-ray was taken for each experimental tooth to observe the filling quality and whether radiographic changes in tissues have occurred.

(3) Macroscopic observation

The animals were sacrificed with an overdose of anesthetic on the 28th and 90th day after the surgery and all teeth containing test and control materials were obtained. The restoration, the teeth and supporting tissues were examined, and details of any abnormalities were recorded. Each treated teeth, together with its surrounding hard and soft tissue were remove, and fixed in a suitable fixing agent. After fixation, the teeth were demineralized with 0.5mol/L EDTA solution at pH7.4. Continuous tissue sections were prepared parallel to the long axis of the tooth through the root canal and its ramifications, showing the material/pulp tissue interface and the adjacent periapical tissues. The sections were 5 μ m ~ 7 μ m thick, and performed with H-E staining.

(4) Histological evaluation

For each series of sections, a full description of all the histological features in the pulp, periapical tissues, dentine and cementum in the apical part of the tooth was recorded. For each specimen, the tissue changes were graded according to scale showing in table 1.

(5) Assessment of results

All information gathered in the test shall be taken into account in assessing the test results, particularly any differences in results between the experimental and control groups. The results of the assessment shall be recorded in the test report.

Table 1. Grading system

Scale	Observation
0	No inflammation
1	Mild inflammation: specimens display a cattering of inflammatory cells, predominately chronic inflammatory cells, and the structural characteristics of residual pulp still identifiable.
2	Moderate inflammation: specimens display focal accumulations of inflammatory cells but no tissue necrosis, and disruption of the structural characteristics of the residual pulp and periapical tissues.
3	Severe inflammation: extensive replacement of the residual pulp or periapical tissues by an inflammatory cell infiltrate
4	Abscess formation

Results

Macroscopic evaluation: During the test period, the animals could eat, no obvious behaviors were normal, and the restoration did not fall off.

Histological evaluation: The histological evaluation results are shown in Table 2. Detailed histological observation results are shown in Appendix 1.

Table 2. Histological evaluation

	28d	90d
Degree of inflammation	Test group: Grade 0, seven; Grade 1, three; Grade 2, zero; Grade 3, zero; Grade 4, zero. Control group: Grade 0, five; Grade 1, zero; Grade 2, zero; Grade 3, zero; Grade 4, zero.	Test group: Grade 0, seven; Grade 1, one; Grade 2, two; Grade 3, zero; Grade 4, zero. Control group: Grade 0, four; Grade 1, zero; Grade 2, one; Grade 3, zero; Grade 4, zero.
Root canal sealer overflow	Test group: zero. Control group: zero.	Test group: zero. Control group: zero.
Degree of root canal filling	Test group: deficient filling, zero; adaptive filling, ten; extra filling, zero. Control group: deficient filling, zero; adaptive filling, five; extra filling, zero.	Test group: deficient filling, zero; adaptive filling, ten; extra filling, zero. Control group: deficient filling, zero; adaptive filling, five; extra filling, zero.
Grade of periapical bone reaction	Test group: normal, seven; inflammation, three. Control group: normal, five; inflammation, zero.	Test group: normal, seven; inflammation, three. Control group: normal, four; inflammation, one.

Conclusion

At the time period of 28 days, among the 10 test specimens, 8 specimens showed no inflammation; 2 specimens of periapical tissue showed mild inflammation; no specimens showed moderate inflammation and severe inflammation. Among the 5 control specimens, there were no specimens showed the inflammation response, and no specimens showed moderate inflammation and severe inflammation. At the time period of 90 days, among the 10 test specimens, 10 specimens showed no inflammation. Among the 5 control specimens, 4 specimens showed no inflammation; 1 specimens of periapical tissue showed moderate inflammation and no specimens showed severe inflammation. Chi-square test showed that there was no significant difference between the control group and the experimental group in the 28-day period ($P>0.05$) and 90-day period of this experiment ($P>0.05$).

Results and conclusions apply only to the test article. No further evaluation of these results is made by Dental Medical Devices Testing Center of Peking University School of Stomatology. Any extrapolation of these data to other samples is the responsibility of the sponsor. All procedures were conducted in conformance with Dental Medical Devices Testing Center of Peking University School of Stomatology Quality System.

Appendix 1. Microscopic observations

28d histological observation								
Control Group								
Code	Tooth position		Inflammation		Degree of root canal filling	Root canal sealer overflow	Periapical tissue reaction	remaining apical pulp
			Scale	Histological description				
1			0	Periapical tissue was intact without inflammatory cells.	deficient	yes	normal ✓	yes
		P3			adaptive ✓	no ✓	inflammation	no ✓
2			0	Periapical tissue was intact without inflammatory cells.	deficient	yes	normal ✓	yes
		P4			adaptive ✓	no ✓	inflammation	no ✓
3		P1	0	Periapical tissue was intact without inflammatory cells.	deficient	yes	normal ✓	yes
					adaptive ✓	no ✓	inflammation	no ✓
4		P2	0	Periapical tissue was intact without inflammatory cells.	deficient	yes	normal ✓	yes
					adaptive ✓	no ✓	inflammation	no ✓
5		P3	0	Periapical tissue was intact without inflammatory cells.	deficient	yes	normal ✓	yes
					adaptive ✓	no ✓	inflammation	no ✓

The histopathological Numbers corresponding to number 1-5 were 191177-6, 191177-7, 191178-3, 191178-4 and 191178-5

28d histological observation								
Test Group								
Code	Tooth position		Inflammation		Degree of root canal filling	Root canal sealer overflow	Periapical tissue reaction	remaining apical pulp
			Scale	Histological description				
1	I3		1	Partial dentin injured. A lot of fibrous tissue and plasma cells scattered between the injured dentin and the surrounding bone. No inflammatory cells were found around periapical tissue.	deficient adaptive ✓ extra	yes no ✓	normal inflammation ✓	yes no ✓
2	P1		0	Periapical tissue was almost intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓
3	P2		0	Periapical tissue was almost intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓
4	P3		1	intact periapical tissue was not seen, and other periapical tissues were hyperemic and hemorrhagic with plasma cell infiltration.	deficient adaptive ✓ extra	yes no ✓	normal inflammation ✓	yes no ✓
5			0	Periapical tissue was intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓
		P2						
6			0	Periapical tissue was intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓
		P2						
7			0	Periapical tissue was intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓
		P3						
8	I2		0	Periapical tissue was intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓
9	I3		0	Periapical tissue was intact without inflammatory cells.	deficient adaptive ✓	yes	normal ✓	yes

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					extra	no ✓	inflammation	no ✓
10			0	Periapical tissue was intact without inflammatory cells.	deficient	yes	normal ✓	yes
		P4			extra	no ✓	inflammation	no ✓
<p>The histopathological numbers corresponding to number 1-10 were 191177-1, 191177-2, 191177-3, 191177-4, 191177-5, 191178-6, 191178-7, 191178-1, 191178-2, 191178-8.</p>								

90d histological observation								
Control Group								
code	Tooth position		Inflammation		Degree of root canal filling	Root canal sealer overflow	Periapical tissue reaction	remaining apical pulp
			Scale	Histological description				
1		I2	2	Periapical tissue was intact, focal accumulations of inflammatory cells can indentifiable	deficient adaptive ✓ extra	yes no ✓	normal inflammation ✓	yes no ✓
2		I3	0	Periapical tissue was intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓
3		P1	0	Periapical tissue was intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓
4		P1	0	Periapical tissue was intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓
5		P2	0	Periapical tissue was intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓

The histopathological Numbers corresponding to Numbers 1-5 were 191179-6, 191179-7, 191179-8, 191151-1, 191151-2.

90d histological observation								
Test Group								
code	Tooth position		Inflammation		Degree of root canal filling	Root canal sealer overflow	Periapical tissue reaction	remaining apical pulp
			Scale	Histological description				
1		P2	0	Periapical tissue was intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓
2		P3	0	Periapical tissue was intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓
3		P4	0	Periapical tissue was intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓
4		P2	0	Periapical tissue was intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓
5		P3	0	Periapical tissue was intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓
6		P3	0	Periapical tissue was intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓
7		P2	0	Periapical tissue was intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓
8		P3	0	Periapical tissue was intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓
9		P4	0	Periapical tissue was intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓
10		I3	0	Periapical tissue was intact without inflammatory cells.	deficient adaptive ✓ extra	yes no ✓	normal ✓ inflammation	yes no ✓

The histopathological Numbers corresponding to the Numbers 1-10 were 191179-1, 191179-2, 191179-3, 191179-4, 191179-5, 191151-3, 191151-5, 191151-6, 191151-7, 191151-4.

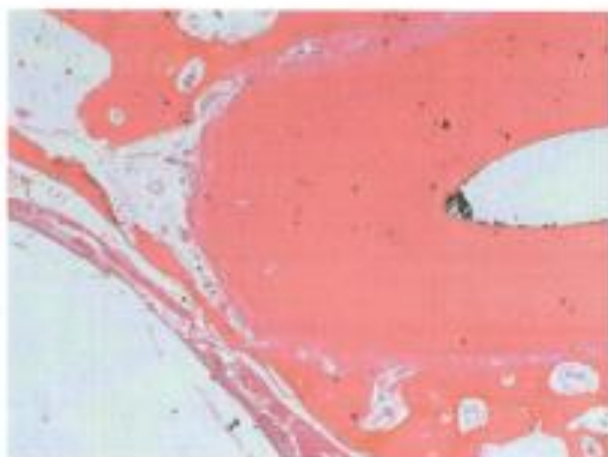
Appendix 2. Histological Pictures



28d- Control-1 (25X)



28d- Control-1 (100X)



28d- Control -2 (25X)



28d- Control -2 (100X)



28d- Control -3 (25X)



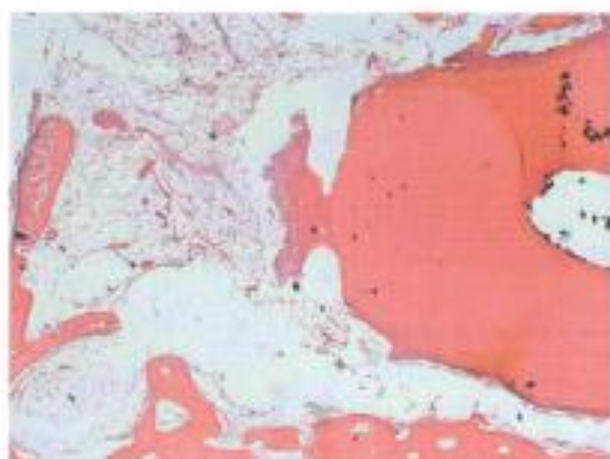
28d- Control -3 (100X)



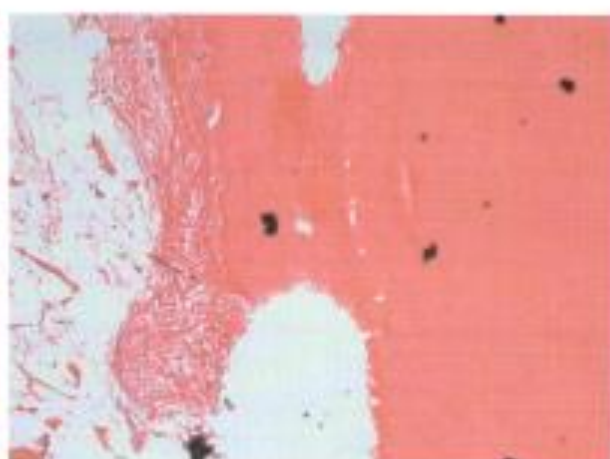
28d- Control - 4 (25X)



28d- Control - 4 (100X)



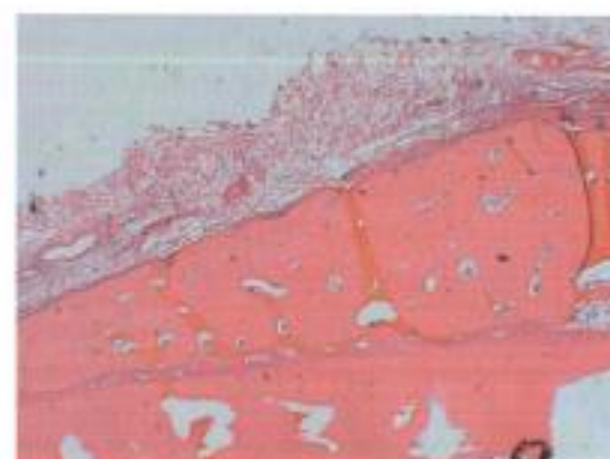
28d- Control - 5 (25X)



28d- Control - 5 (100X)



28d- Test- 1 (25X)



28d- Test- 1 (100X)



28d- Test- 2 (25X)



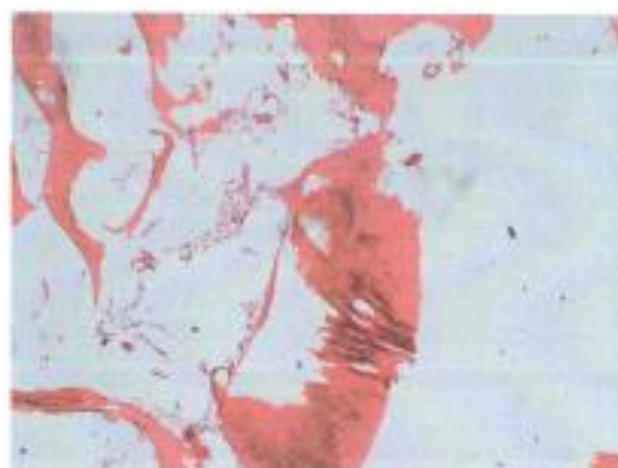
28d- Test- 2 (100X)



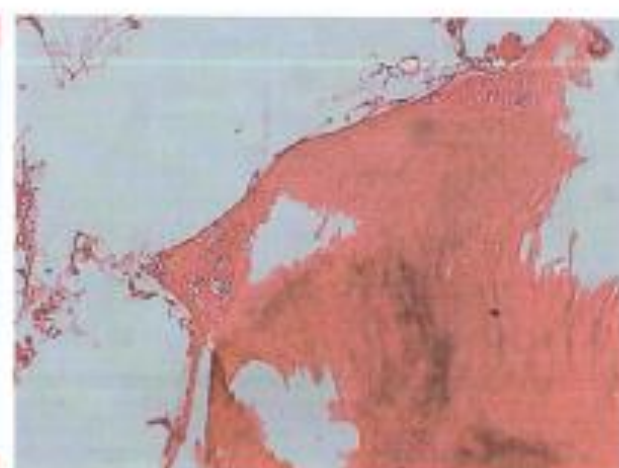
28d- Test- 3 (25X)



28d- Test- 3 (100X)



28d- Test- 4 (25X)



28d- Test- 4 (100X)



28d- Test- 5 (25X)



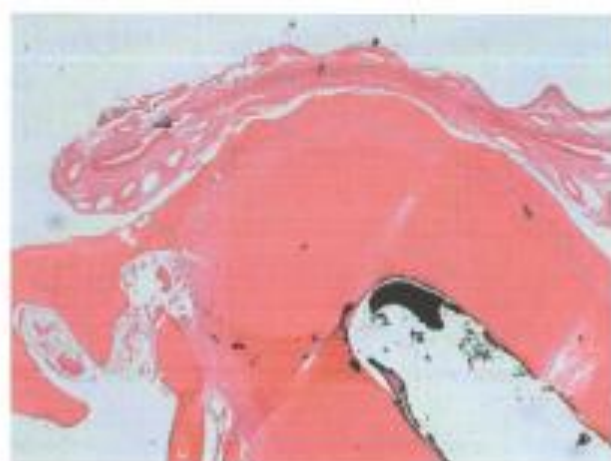
28d- Test- 5 (100X)



28d- Test- 6 (25X)



28d- Test- 6 (100X)



28d- Test- 7 (25X)



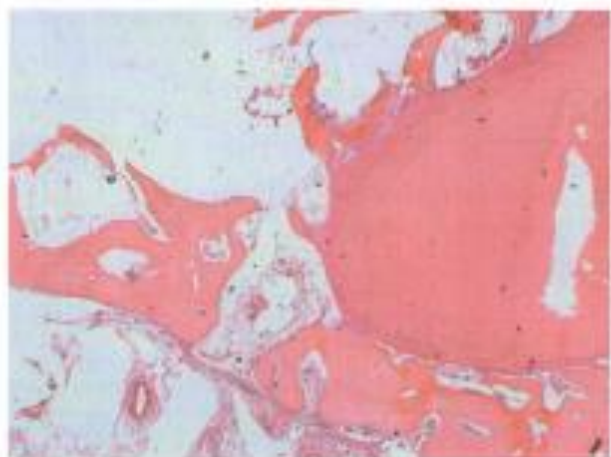
28d- Test- 7 (100X)



28d-Test-8 (25X)



28d-Test-8 (100X)



28d-Test-9 (25X)



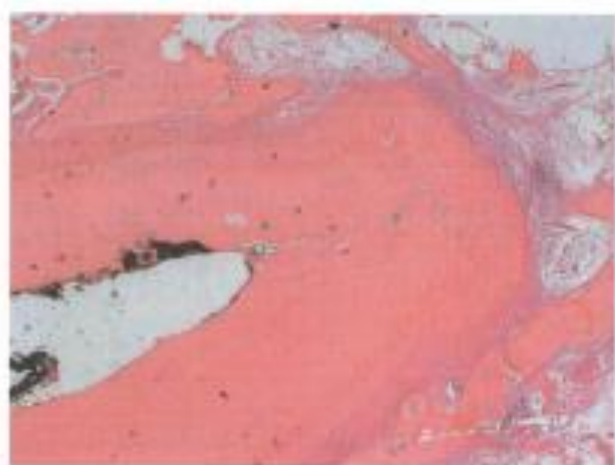
28d-Test-9 (100X)



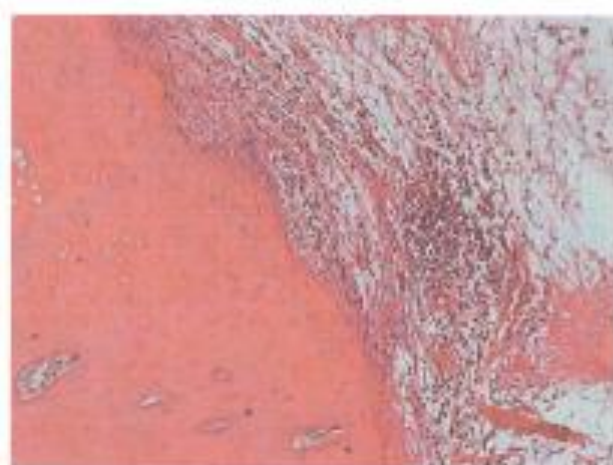
28d-Test-10 (25X)



28d-Test-10 (100X)



90d- Control- 1 (25X)



90d- Control- 1 (100X)



90d- Control- 2 (25X)



90d- Control- 2 (100X)



90d- Control- 3 (25X)



90d- Control- 3 (100X)



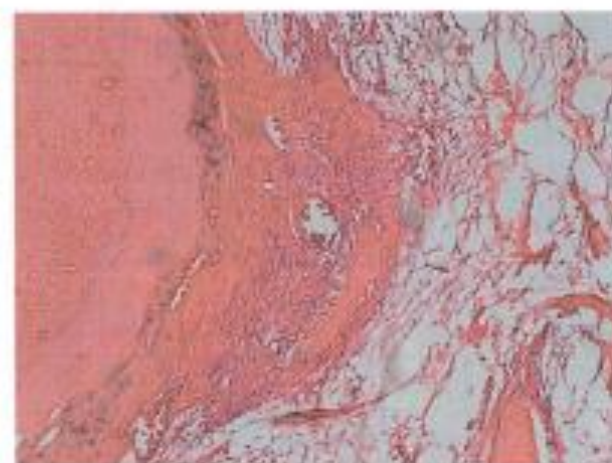
90d- Control- 4 (25X)



90d- Control- 4 (100X)



90d- Control- 5 (25X)



90d- Control- 5 (100X)



90d- Test- 1 (25X)



90d- Test- 1 (100X)



90d- Test- 2 (25X)



90d- Test- 2 (100X)



90d- Test- 3 (25X)



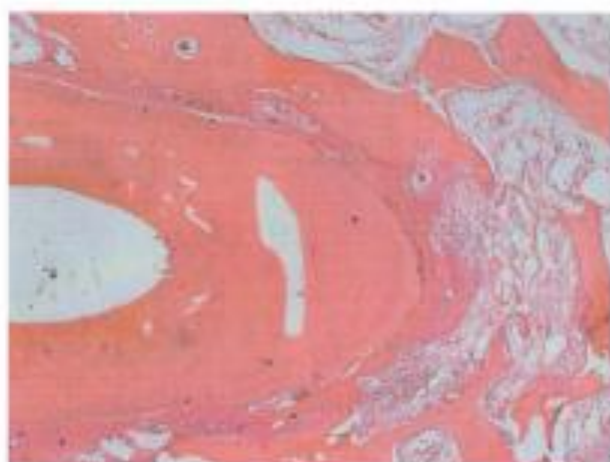
90d- Test- 3 (100X)



90d- Test- 4 (25X)



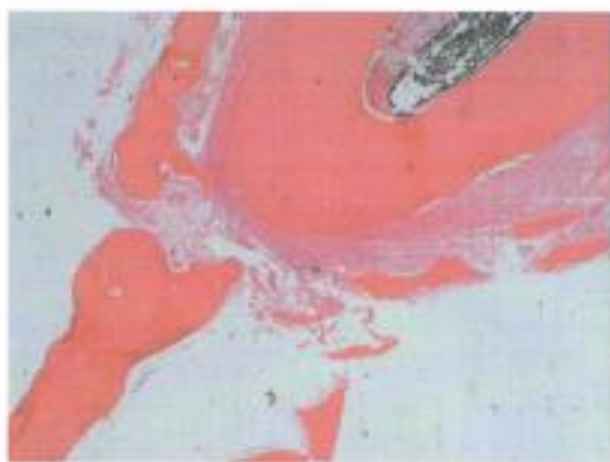
90d- Test- 4 (100X)



90d- Test- 5 (25X)



90d- Test- 5 (100X)



90d- Test- 6 (25X)



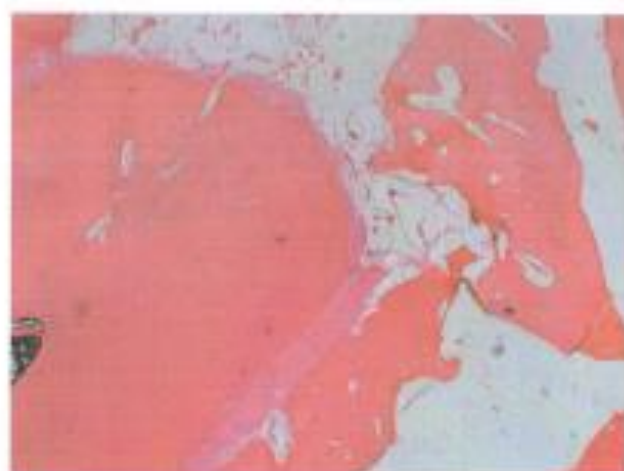
90d- Test- 6 (100X)



90d- Test- 7 (25X)



90d- Test- 7 (100X)



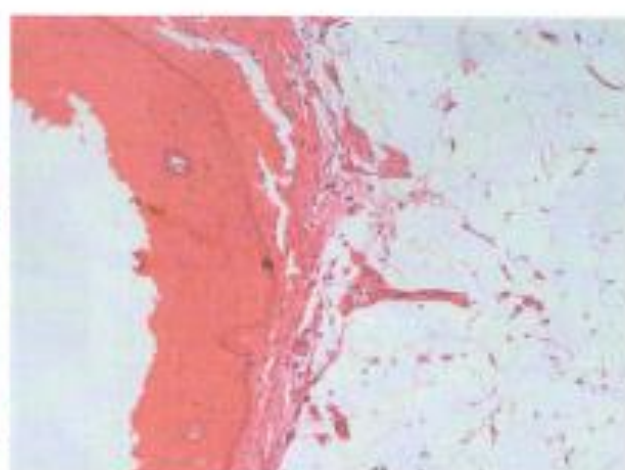
90d- Test- 8 (25X)



90d- Test- 8 (100X)



90d- Test- 9 (25X)



90d- Test- 9 (100X)



90d- Test- 10 (25X)



90d- Test- 10 (100X)