UNIVERSITY of ROCHESTER MEDICAL CENTER

EASTMAN INSTITUTE FOR ORAL HEALTH

Healing of Human Extraction Sockets After the Use of Foundation™

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ABSTRACT

Objective: To assess the healing of human extraction sockets following the grafting of Foundation™, a collagen-based socket preservation material (J. Morita USA; manufactured by Olympus-Terumo Biomaterials, Tokyo, Japan). Methods: Eighteen subjects (10 males and 8 females) who were scheduled for extraction (10 molars, 5 premolars and 3 incisors) participated in this study. Immediately after the tooth extraction under local anesthesia, the Foundation graft was inserted into the extraction sockets and sutured in place. Biopsies from the healed extraction sites were done using trephine osteotomy at 8 weeks after grafting at the time of implant placement.

Acid-etched Sterngold Implamed root-form dental implants (3.75 to 5.0mm in diameter, 8.5 to 13.0mm in length) were inserted into the osteotomy sites and allowed to heal for 2 to 3 months before final restoration with porcelain-fused-to-metal crowns. The cylindrical bone segments obtained by biopsy were scanned with a high-resolution micro-computed tomography (μCT, vivaCT 40, Scanco Medical) to determine the value of the total volume of the contoured callus area (TV), the bone volume (BV) within contoured TV, the BV/TV ratio, and the average density of the bone compared to the hydroxyapatite (HA) calibration standard. The specimens were decalcified using 10% EDTA, embedded, sectioned, and stained with hematoxylin and eosin.

New bone formation was identified using polarized microscopy. The expression of osteoblast activity during bone healing was evaluated by the immunohistochemical method for BMP-2 and PDGF-B.

Results: Histology results from the sections showed very active stages of woven bone formation. A majority (86%) of the bone biopsy specimens were comprised of newly formed woven bone (range 72-97%). BMP-2 and PDGF-B positive osteoblasts were observed lining the edge of the newly formed woven bone, indicating an active process of bone formation. μCT showed a mean BV/TV of 52%, and a mean mineral density of 865mm HA/ccm, signifying that the extraction sites were still undergoing a healing process towards the formation of mature lamellar bone.

BACKGROUND

For the successful placement of dental implants, and to fulfill functional and esthetic demand, a sufficient amount of alveolar ridge is required. Following the tooth extraction, the healing process usually occurs with substantial reduction of the original height and width of the alveolar bone (Amler 1969; Mecall and Rosenfeld 1991; Araujo and Lindhe 2005). To preserve the alveolar ridge, many studies have been conducted using various graft materials including autogenous, allogenous, xenogenic and alloplastic bone graft (Artzi Tal and Dayan 2000; Becker et al 1998; Carmagnola Adriaens and Berglundh 2003; Dies et al 1998; Froum et al 2002; Guarnieri et al 2004; Iasella et al 2003; Sandor et al 2003). Controversy still exists, however, on what constitutes ideal socket preservation material.

Foundation is a collagen-based bone filling augmentation material for use in the filling of extraction sockets. It consists of fibrillar that provides scaffolding for cell attachment and promotes the faster growth of bone (Turchi 2007). Today, there is very limited information focusing on detailed characterization of bone healing in human extraction sockets. Therefore, our study was to assess the quality of newly formed bone in human extraction sockets after the use of Foundation.

MATERIALS AND METHODS

Study Population

18 subjects (10 males and 8 females), participated in this study.

Inclusion Criteria

- 18 years of age or older (in good physical and mental health). One to two teeth in maxillary or mandibular dentitions in need of extraction due to caries related infections, root fracture, trauma and failed root canal therapy. Proximal and distal teeth must be present and free from periodontal diseases.
- Be able to sign an informed consent.

Exclusion Criteria

- Allergic to products containing bovine collagen.
- Significant buccal and palatal wall bone loss (more than 50%).
- Significant bone resorption of adjacent teeth due to periodontal diseases.
- Smoking.
- Immune compromised individuals.
- Medical condition which requires premedication prior to dental procedures/visits.
- Subjects unable or unwilling to sign the informed consent form.
- Pregnant or nursing women.
- Participation in any other clinical study or test panel within 2 weeks prior to enrollment into this study.
- Patients who do not read or speak English.

Timeline of the Study

Day 0	2-month	5-month	8-month	11-month
Exo+ Foundation	Implant	Restorative	Follow up 1	Follow up 2

Socket Preservation Material

Foundation

Foundation is a biodegradable bone augmentation material made from bovine atelo-collagen. Foundation is placed into the socket immediately after tooth extraction. It is shaped in bullet form for easy placement and is available in both small (S) and medium (M) sizes. Since it is a biodegradable material, there is no need to remove it and no membrane is required.

Conclusion

Foundation, an atelo-collagen, is biocompatible and promotes bone growth after tooth extraction. It appears to be a suitable grafting material for socket preservation prior to implant placement.

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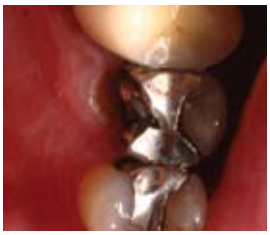
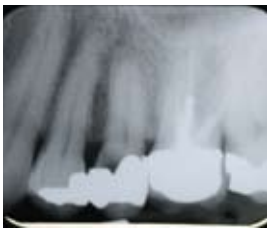
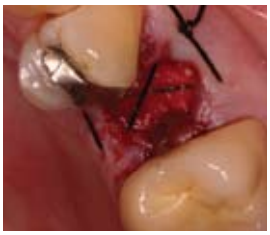
SUBJECT PROCEDURES

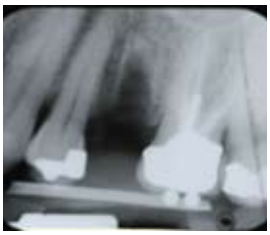
Pre-op for tooth #13



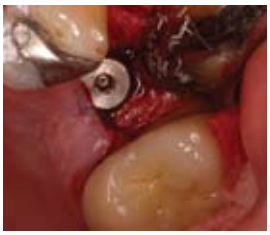


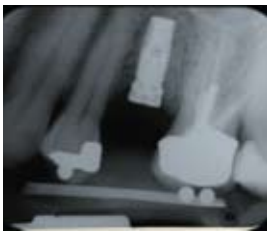
Post ext. #13, Foundation placed



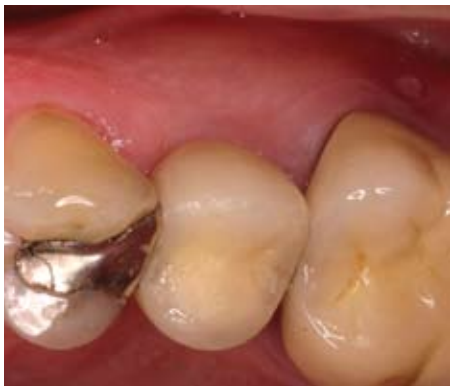


2 months post ext. #13



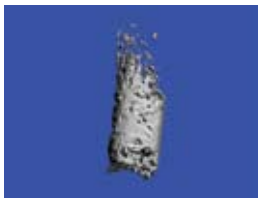


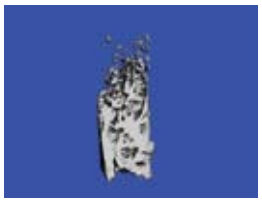
5 months post ext. #13



SAMPLES PROCESSING

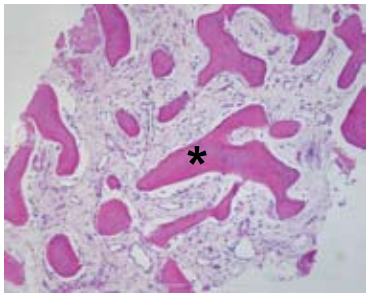
3D µCT images of the bone biopsy



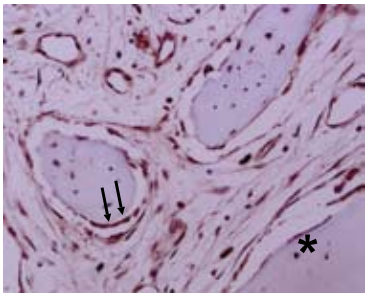


Subject ID	Tooth #	Gender	TV (mm3)	BV (mm3)	BV/TV	Density (mm HA/ccm)
1	4	F	25.584	10.386	0.406	742.619
2	7	F	14.575	1.92	0.132	653.099
3	8	M	18.676	9.655	0.517	809.941
4	13	M	14.478	6.857	0.474	770.421
5	19	F	59.956	30.853	0.515	944.803
6	19	M	78.199	46.882	0.599	919.185
7	19	M	76.63	46.942	0.613	918.966
8	30	F	87.288	50.04	0.573	914.818
9	19	F	68.326	29.396	0.43	808.995
10	19	F	57.307	24.855	0.43	843.129
11	14	M	107.31	50.98	0.475	895.822
12	12	F	107.39	67.83	0.63	950.335
13	30	M	96.18	52.36	0.544	868.238
14	28	M	24.284	12.61	0.52	840.508
15	13	M	34.99	3.35	0.096	664.089
16	30	M	25.88	15.02	0.58	843.93
17	13	F	73.894	30.732	0.416	915.32

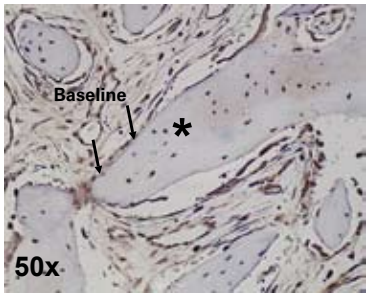
H&E (50x)



BMP-2 (200x)



PDGF-B (200x)



Immunohistochemistry: To histologically evaluate the prescence of active osteoblasts during the bone healing process, an anti-BMP-2 antibody (Santa Cruz Biotech, Inc. USA) and anti-PDGF-B antibody (Santa Cruz Biotech, Inc. USA) were used.