Labrida BioClean® - Studies “in short”

In vitro studies

Wohlfahrt et al. 2012. **A SEM analysis of titanium implant surfaces after instrumentation with Labrida BioClean or titanium curette,** unpublished data (included in Technical file)

Three titanium implant surfaces (smooth, machined, and rough) were either untreated or instrumented for 30 seconds with a titanium curette or with Labrida BioClean®. The surfaces were analysed with SEM for any changes in structure. Treatment with titanium curette had a significant effect on the surfaces (grooves and flattening) on all implant surfaces. Treatment with Labrida BioClean® did not cause any noticeable changes on the implant surfaces.

Larsen et al. 2017. **Antimicrobial effects of three different treatment modalities on dental implant surfaces, J of Oral Implantology**, Vol. XLIII/No. Six/2017,429-436

Assessment of 1) Antimicrobial effect of YAG laser, Labrida BioClean® and titanium curette on a rough implant surface contaminated with the periodontitis bacterium *Porphyromonas gingivalis* art, and 2) Changes in the implant surface after instrumentation.

1) There was no significant difference between the three different groups when it came to decontamination. All instruments significantly reduced the number of *P. gingivalis* on the implant surface

2) The titanium curette significantly changed the structure of the implant surface. Neither the YAG laser nor Labrida BioClean® altered the implant surface significantly.

Animal study

Villa et al. **Suture materials affect peri-implant bone healing and implant osseointegration,** J Oral Sci. 2015 Sep;57(3):219-27

Rabbit tibia model, - filaments of non-resorbable nylon or resorbable chitosan were placed at the interface between bone and implant surface. Control sites did not have suture material. 4 weeks of healing. Enzymatic assays and mRNA quantification of bone-related and cytokine markers from the peri-implant bone were performed. Peri-implant bone healing was marginally affected by the two suture materials. A tendency for better osseointegration and lower increase in bone resorption markers were observed in the group receiving chitosan sutures, compared with the control group.

Clinical studies

Wohlfahrt et al.**Treatment of Peri-Implant mucositis using a resorbable chitosan brush – a pilot clinical study** EAO 22nd annual scientific meeting, poster presentation, Dublin 2013

Pilot study, 6 months duration, 13 patients with peri-implant mucositis were treated with Labrida BioClean® (at BL and 3 months). Significant improvement in the clinical parameters (PPD, mBI, BoP) was demonstrated.

Zeza, Wohlfahrt and Pilloni, **Chitosan brush for professional removal of plaque in mild peri-implantitis,** Minerva Stomatol 2017 Aug;66(4):163-168

See Wohlfahrt et al, 2017

Wohlfahrt et al, **A novel non-surgical method for mild peri-implantitis - a multicenter, consecutive case series** Int. J Implant Dent 2017 Dec;3(1):38 ePub Aug 2017 and EAO 24th annual scientific meeting, poster presentation, Paris 2016

Multicenter (6 clinics), consecutive case series, - 6 months duration, 63 implants in 63 patients with mild peri-implantitis were included. Patients were clinically examined at BL and 2, 4, 12, and 24 weeks, and the implants were treated with Labrida BioClean® at BL and 3 months. Reduction in PPD and mBoP was compared between BL and the later time points. Significant reductions in both PPD and mBoP were observed at all time points, compared with BL. Stable reduction in PPD and mBoP was evident up to 6 months after the first treatment and 3 months after the second treatment. There was no difference in the results between the different centers. All 63 implants had a stable bone level. Labrida BioClean® is safe to use and appears to have a positive effect on non-surgical treatment of dental implants with mild peri-implantitis.

Wohlfahrt JC, Aass AM, Koldsland OC **Treatment of peri-implant mucositis with a chitosan brush-A pilot randomized clinical tria**l. Int J Dent Hyg. 2019;17:170-176

Pilot RCT, 6 months duration, 11 patients with a total of 24 implants and with peri-implant mucositis were randomized to treatment with either Labrida BioClean® or titanium curette. Treatment at BL and 3 months. Changes in clinical parameters were compared between the groups at 2 weeks, 4 weeks and 6 months. Both groups showed a significant reduction in mBoP between BL and 6 months. The test implants treated with Labrida BioClean® showed better improvement in mBoP at 2 and 4 weeks, compared to the implants treated with titanium curette. Reduction in PPD was significantly better for the test group at 4 weeks. All implants had a stable bone level.

Samuelsson and Wohlfahrt, **Non-surgical treatment of peri-implantitis using a chitosan brush with adjunctive chemical decontaminants – a retrospective case series,** IJOMI, 37(6), 2022, 1261-1267

Retrospective case series, 22 patients with 25 implants with moderate to advanced peri-implantitis. Patients were treated with three repeated non-surgical maintenance treatments with Labrida BioClean®, with H_2O_2 (3%) and Tetracycline-HCl as chemical detergents (three treatments at 2–3-week intervals). Clinical examinations (CAL and mBoP) and X-rays were performed before starting the treatment, as well as at the follow-up consultations. Patients were examined after at least 6 months and up to 36 months after the first treatment. 20 patients showed improvement in CAL and BoP between BL and the examinations at 6 and up to 36 months after treatment. All of these patients had stable bone levels.

Hussain et al, **Treatment of residual pockets using an oscillating chitosan device versus regular curettes alone – A randomized feasibility parallel-arm clinical trial,** J of Periodontol., 2021,1-10

Seventy-eight patients with periodontitis were included in this multicentre, randomized, examiner-blind clinical trial of 6 months duration. 78 patients with residual probing pocket depth (PPD) of ≥5mm and ≤7mm following previous active periodontal treatment were included. Patients were assigned either subgingival treatment with curettes (control) or an oscillating chitosan brush (test). Changes in bleeding on probing (BoP) and PPD between baseline and terminal evaluation at 6 months were evaluated.

A significant reduction in both PPD and BoP was seen within both groups. There was no significant difference in BoP between test and control groups after 6 months, but the reduction in PPD was significantly improved in the test group ($P \leq 0.01$). The combined outcome of no BOP and PPD ≤4mm was significantly better in the test group ($P \leq 0.01$). No adverse reactions were seen.
Treatment of residual periodontal pockets (PPD = 5 to 7 mm) with a chitosan brush disclosed equal or better clinical results as compared to regular curettes. This study supports that a chitosan brush can be used for subgingival biofilm removal and soft tissue curettage in the treatment of periodontitis.

Kahn et al, **Non-surgical treatment of mild to moderate peri-implantitis using an oscillating chitosan brush or a titanium curette—A randomized multicentre controlled clinical trial,** Clin Ora Impl Res.2022;00:1-11

This prospective, parallel-group, examiner-blinded, multicentre, randomized, controlled clinical trial aimed to assess the efficacy of an oscillating chitosan brush (OCB) versus titanium curettes (TC) on clinical parameters in the non-surgical treatment of peri-implantitis.

Thirty-nine patients with one implant with mild to moderate peri-implantitis, defined as 2–4 mm radiographic reduced bone level, bleeding index (BI) ≥ 2, and probing pocket depth (PPD) ≥ 4 mm were randomly allocated to test and

control groups, receiving OCB or TC debridement, respectively. Treatment was performed at baseline and three months. PPD, BI, and Plaque index (PI) were measured at six sites per implant and recorded by five blinded examiners at baseline, one, three, and six month(s). Pus was recorded as present/not present. Changes in PPD and BI were compared between groups and analysed using multilevel partial ordinal and linear regression.

Thirty-eight patients completed the study. Both groups showed significant reductions in PPD and BI at six months compared with baseline ($p < .05$). There was no statistically significant difference in PPD and BI changes between the groups.

Eradication of peri-implant disease as defined was observed in 9.5% of cases in the OCB group and 5.9% in the TC group.

Kahn et al, **Non-surgical treatment of mild to moderate peri-implantitis using an oscillating chitosan brush or a titanium curette—12-month follow-up of a multicentre randomized clinical trial,** Clin Ora Impl Res.2023;00:1-14

The prospective, parallel-group, examiner-blinded, multicentre, randomized, controlled clinical trial aimed to assess the efficacy of an oscillating chitosan brush (OCB) versus titanium curettes (TC) on clinical parameters in the non-surgical treatment of peri-implantitis.

Thirty-nine patients with one implant with mild to moderate peri-implantitis, defined as 2–4 mm radiographic reduced bone level, bleeding index (BI) ≥ 2, and probing pocket depth (PPD) ≥ 4 mm were randomly assigned to mechanical debridement with OCB (test) or TC (control). Treatment was performed at baseline and repeated at 3, 6 and 9 months in cases with > 1 implant site with BI ≥ 1 and PPD ≥ 4mm. Blinded examiners recorded PPD, BI, pus and plaque. A multistate model was used to calculate transitions of BI. Thirty-one patients completed the study. Both groups exhibited a significant reduction in PPD, BI, and pus at 12 months compared to baseline. Radiographic analysis showed stable mean RBL in both groups at 12 months. There was no statistically significant difference in any of the parameters between the groups.

Clinical improvements and, in some cases, disease resolution, were observed in both groups. Persistent inflammation was a common finding which puts emphasis on the need for further treatment.

Third Party Publications

Mayer et al, **A nonsurgical treatment of peri-implantitis using mechanic, antiseptic and ant-inflammatory treatment: 1 year follow up,** Clin Exp Dent Res. 2020;1-8, https://doi.org/ 10.1002/cre2.286

Labrida BioClean® combined with chemical decontaminants provides good clinical improvement after 1 year.

Koldsland et al, **Supportive treatment following peri-implantitis surgery: An RCT using titanium curettes or chitosan brushes,** J Clin Periodontol. 2020;47:1259-1267

Labrida BioClean® is just as good as curettes in «SPIT» (Supportive peri-implant treatment), used every 3rd months on patients with progressive peri-implantitis, and having undergone surgery.

Supporting Literature

Costa et al, **Peri-implant disease in subjects with and without preventive maintenance: a 5-year follow-up,** J Clin Periodontol. 2012 Feb;39(2):173-81.

Prospective cohort study, 5 years follow-up of 80 patients diagnosed with mucositis at the baseline examination, 41 patients with peri-implant regular maintenance and 39 patients without peri-implant regular maintenance Results: Higher incidence of peri-implantitis in patients without compared to patients with regular peri-implant maintenance during the 5 years follow-up period (43.9% vs.18%)

Conclusion: Regular peri-implant maintenance care prevents development of peri-implantitis

Costa et al, **Antimicrobial Effect of Chitosan against Periodontal Pathogens Biofilms,** Micriobiol Infect Dis 2(1): 1-6. DOI: http://dx.doi.org/10.15226/sojmid.2014.00114

Eger et al, **Scaling of titanium implants entrains inflammation-induced osteolysis,** www.nature.com, Scientific Reports | 7:39612 | DOI: 10.1038/srep39612

Mann et al, **Effect of plastic-covered ultrasonic scales on titanium implant surfaces,** Clin Oral Implants Res. 2012 jan;23(1):76-82

Jepsen et al**, Primary prevention of peri-implantitis: managing peri-implant mucositis**, J Clin Periodontol.2015 Apr;42 Suppl.16:S152-7