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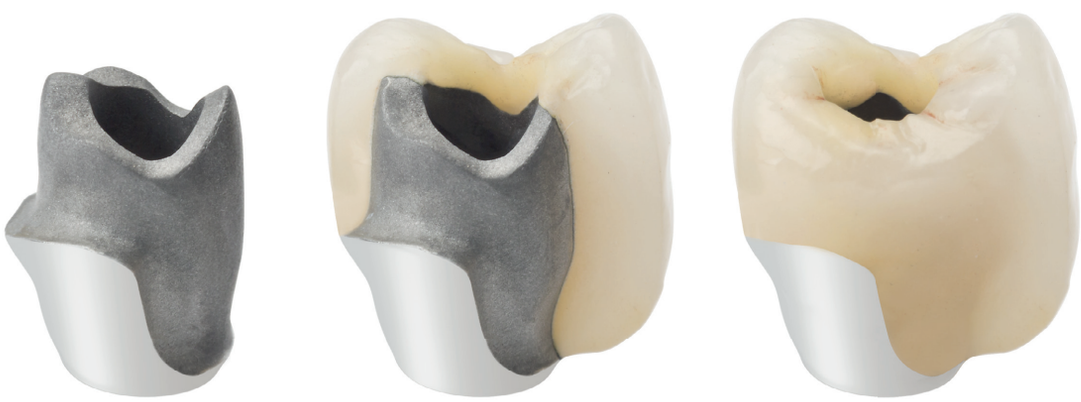
LaserAbutments™ - clinical evidence

LaserAbutments

1. Introduction

This document presents clinical evidence relevant to Renishaw LaserAbutments. It is drawn from a variety of sources, including published literature, international standards and in-house testing. References are provided; further reading is also shown at the end of this document. If you have questions or comments please contact Renishaw Dental Support [1].



2. Electrocorrosion and galvanic reactions

Placing Renishaw LaserAbutments onto titanium implants does not increase the risk of electrocorrosion or galvanic reaction compared to titanium abutments on titanium implants.

Electrocorrosion and galvanic reactions are always a possibility in the oral cavity, especially if dissimilar metals are in contact with each other in the presence of an electrolyte. However it is possible for electrocorrosion to occur even in a single metallic restoration if it has local variations in composition (e.g. impurities), if it is in contact with electrolyte of varying composition (e.g. fresh, aerated saliva and deoxygenated, acidified saliva in sulci) or if it has a poor surface finish (pitting) [i,ii].

In an in vitro study [iii], sections of Cresco cobalt chromium (CoCr) implant bridges (Astra Tech, Mölndal, Sweden) were immersed in artificial saliva (composition to ISO 10993-13, temperature 37°C, pH 6.7). Control samples (n=3) were left unattached; test samples (n=3) were attached to titanium (Ti) implants (Brånemark Mk IV RP, Nobel Biocare, Zurich, Switzerland). Ion leakage was measured using inductively coupled plasma mass spectrometry (ICP-MS).

Figure 1, overleaf, shows mean ICP-MS Co ion concentrations over a period of 30 days (error bars show the measurement ranges) [iv]. Cr and Ti ion concentrations were over 2 orders of magnitude lower and are therefore not shown.

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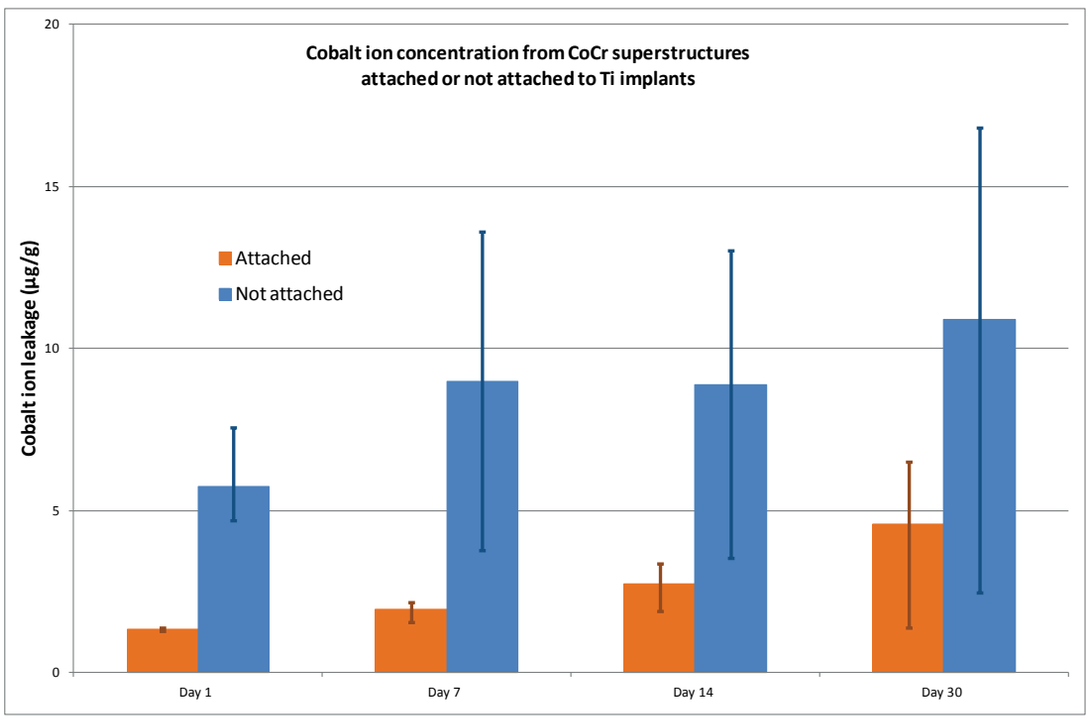

Figure 1

Cresco CoCr implant bridges are made from Wirobond SG & C, (BEGO, Bremen, Germany); Renishaw LaserAbutments are made from LaserPFM CoCr (Renishaw, Wotton-under-Edge, UK). A comparison of these materials is shown in Table 1, below.

Element	Wirobond [v] SG & C	LaserPFM [vi]
Co	63.3	63.8
Cr	24.8	24.7
W	5.3	5.4
Mo	5.1	5.1
Si	<1	1.0
Fe	<1	<0.5
Ce	<1	-
Mn	-	<0.1

Table 1

We conclude that this study demonstrates that LaserAbutment contact with Ti implants will not significantly increase electrocorrosion and galvanic reaction.

3. Clinical performance

In an in vivo clinical trial [vii], complications and survival rates were compared for Cresco CoCr and Ti implant-level bridges (Astra Tech, Mölndal, Sweden). Figures 2 and 3 below report survival rates [viii] and clinical complications [ix] after 5 years.

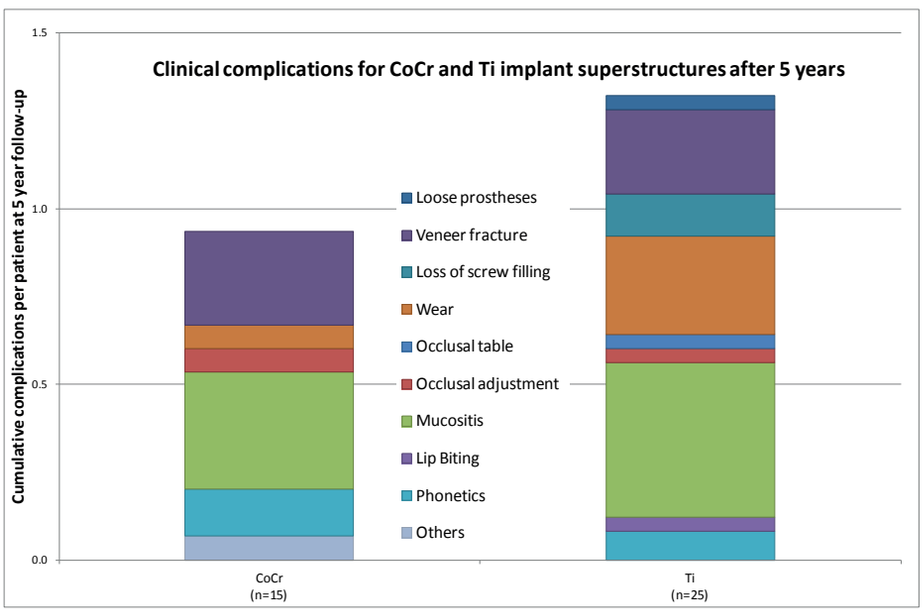

Figure 2

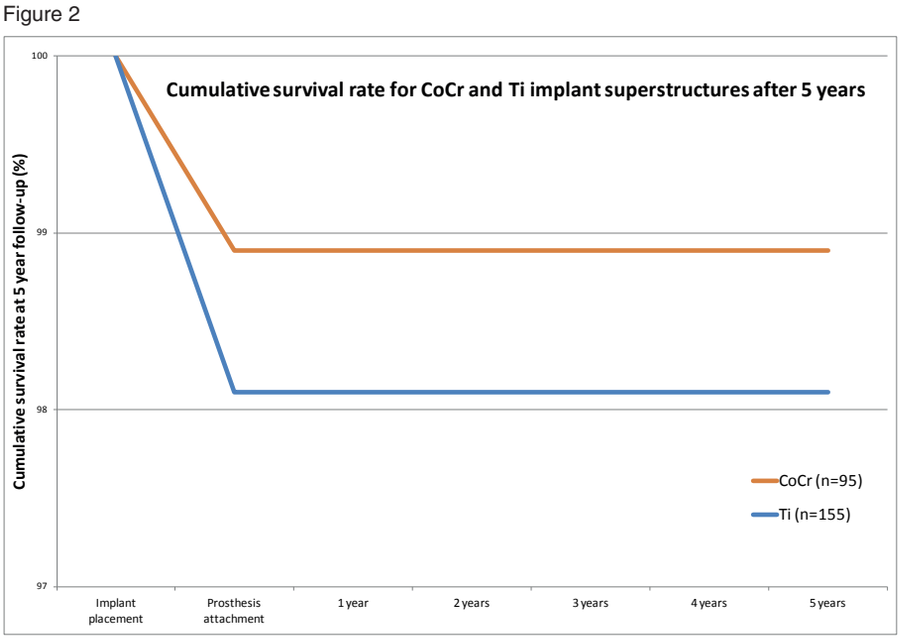

Figure 3

The author of the study observes that there are no statistically significant differences in the cumulative survival rates or clinical complication rates between Cresco-CoCr and Cresco-Ti.

We conclude from this in vivo clinical trial that LaserAbutment CoCr superstructures on Ti implants will offer similar clinical performance compared to Ti superstructures.

4. Pre-polished emergence profile

Abutment surface roughness has been shown to be associated with bacterial adhesion and plaque formation [x]. The emergence profile of LaserAbutments has been designed to be smooth to reduce the risk of bacterial adhesion and plaque formation. LaserAbutments are supplied with a pre-polished emergence profile eight times smoother than the milled titanium equivalent.

In an in vitro trial [xi] surface finish measurements were independently made using an inductive profilometer (Form Talysurf Intra, Taylor Hobson, Leicester, UK) on the emergence profiles of abutments. Measurements were made on a machined Ti abutment and an ionic hyper-polished CoCr LaserAbutment. Figure 4, below, shows surface finish profiles. Surface finish parameter, Ra (the arithmetic mean of the absolute values of vertical profile), was calculated from these profiles and is shown in Table 2, below.

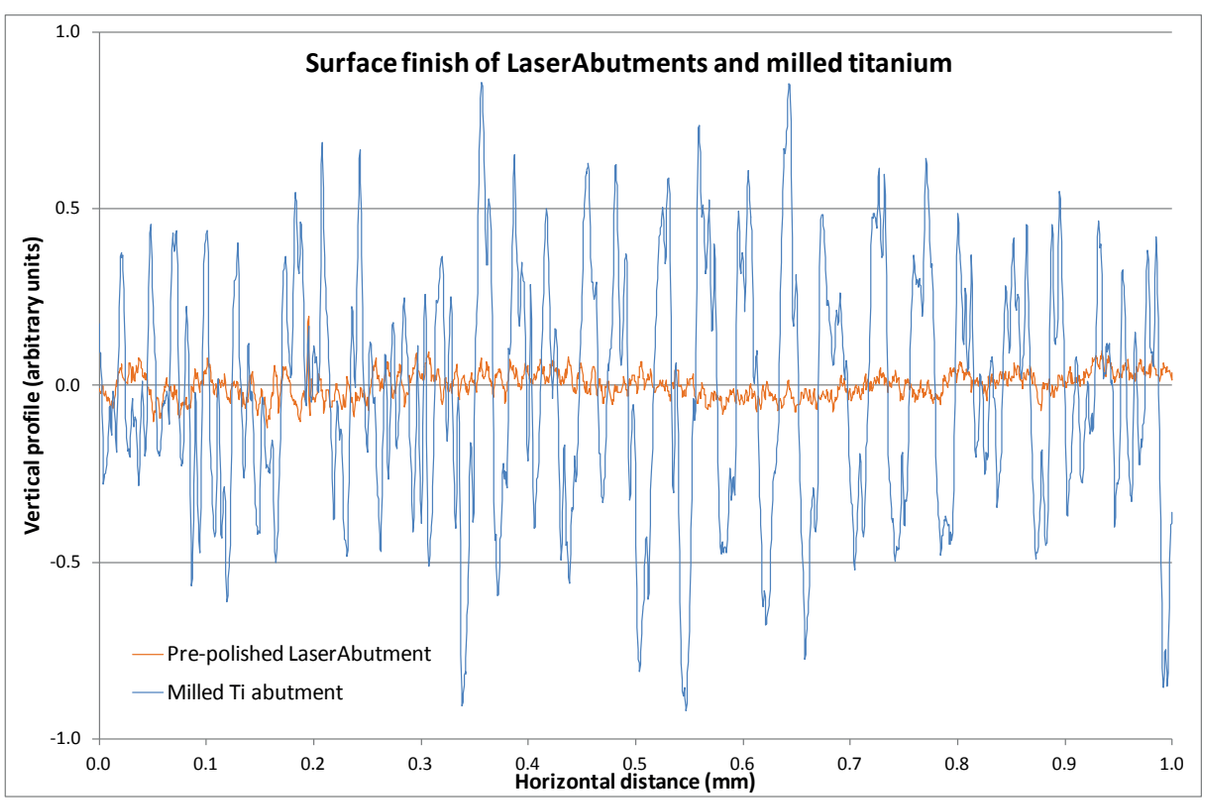

Figure 4

	LaserAbutment	Milled Ti abutment
Ra (µm)	0.031	0.246

Table 2

We conclude that the CoCr LaserAbutment emergence profile is eight times smoother than the milled Ti equivalent.

5. Fatigue strength

Abutments and retaining screws are subject to cyclic loads in vivo, and fatigue strength is a critical requirement. LaserAbutments outperform titanium equivalents in fatigue tests, showing an increase in strength of more than 12.5%.

Hundreds of hours of state-of-the-art finite element analysis (FEA) have been performed to compare the performance of Renishaw LaserAbutments with current market leaders [xii], Figure 5. This FEA has been used to identify the implant interface and size combination which impose the highest stresses on the abutment.

Renishaw LaserAbutments have then been independently tested in an in vitro study to ensure that they are at least as strong as a Ti equivalent [xiii]. Custom 30° angled LaserAbutments (test, n=10) and the Ti equivalents (control, n=5) have been designed, manufactured and fatigue tested in accordance with ISO 14801 (see standards, overleaf). The results of this testing are shown in Figure 6.

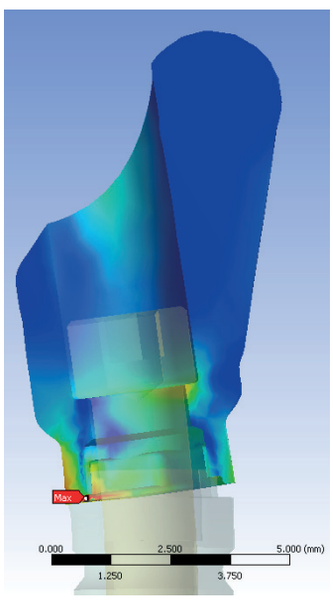

Figure 5

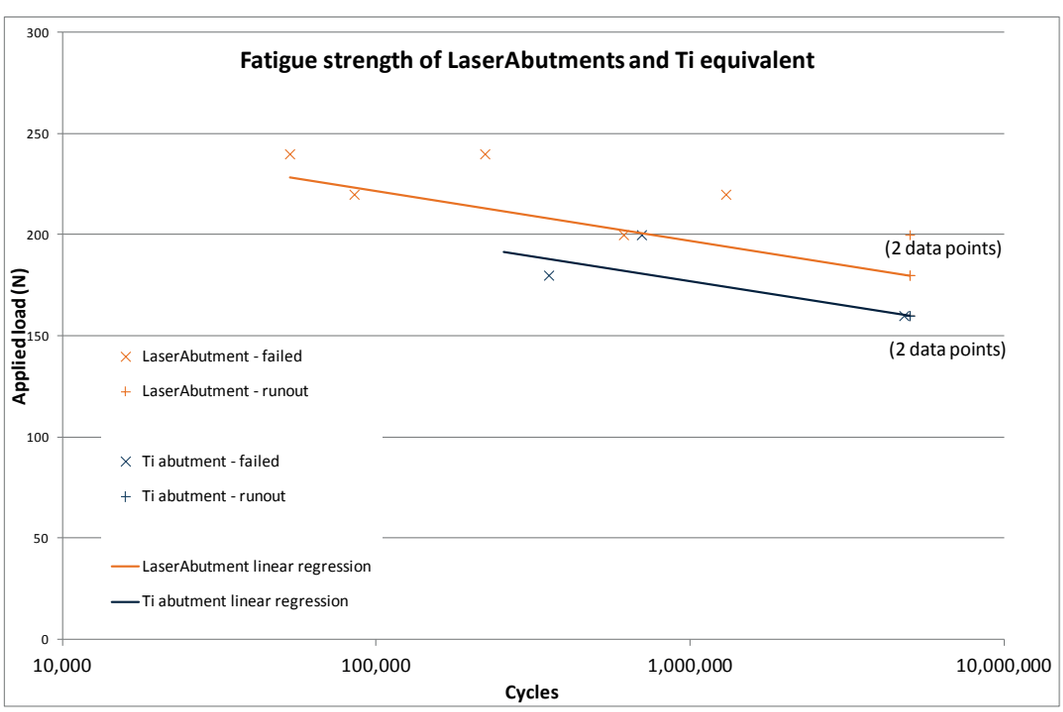

Figure 6

We conclude that the maximum endured load (the maximum load at which at least three abutments reach 5 million cycles without failure) for LaserAbutments is more than 12.5% greater than for equivalent titanium components.

6. Standards

The standards shown in Table 3, below, have been used in the design and production of Renishaw LaserAbutments.

Standard	Summary
BS EN 1642:2011 Dentistry. Medical devices for dentistry. Dental implants	This standard details requirements applicable to dental implants and abutments and has been used in the design of Renishaw LaserAbutments.
BS EN ISO 10993-1:2009 Biological evaluation of medical devices. Evaluation and testing within a risk management process	This is the top-level standard for biocompatibility testing of medical devices and outlines the approach to be taken.
BS EN ISO 10993-3:2009 Biological evaluation of medical devices. Tests for genotoxicity, carcinogenicity and reproductive toxicity	Renishaw LaserAbutments have been successfully tested for genotoxicity according to the method specified in this standard
BS EN ISO 10993-5:2009 Biological evaluation of medical devices. Tests for in vitro cytotoxicity	Renishaw LaserAbutments have been successfully tested for cytotoxicity according to the method specified in this standard.
BS EN ISO 10993-10:2010 Biological evaluation of medical devices. Tests for irritation and skin sensitization	Renishaw LaserAbutments have been successfully tested for intracutaneous irritation and sensitisation according to the method specified in this standard.
BS EN ISO 10993-11:2009 Biological evaluation of medical devices. Tests for systemic toxicity	Renishaw LaserAbutments have been successfully tested for acute systemic toxicity according to the method specified in this standard.
BS EN ISO 13485:2003 Medical devices. Quality management systems. Requirements for regulatory purposes	This standard defines requirements for medical device quality management systems to meet, e.g., the requirements of the medical device directive, and is used in the design and production of Renishaw LaserAbutments.
BS EN ISO 14801:2007 Dentistry. Implants. Dynamic fatigue test for endosseous dental implants	This standard defines the test to be used in assessing the fatigue strength of dental implants and abutments. Renishaw LaserAbutments have been successfully tested against this standard.
BS EN ISO 14971:2009 Medical devices. Application of risk management to medical devices	This standard specifies procedures and tools used in the risk management of medical devices and has been used in the design and manufacture of Renishaw LaserAbutments.
BS EN ISO 22674:2006 Dentistry. Metallic materials for fixed and removable restorations and appliances	This standard specifies requirements for metals used in dental restorations. The CoCr material used to manufacture Renishaw LaserAbutments meets the requirements of this standard.

Table 3

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7. Further reading

The following papers may be of interest to the reader. Links may be found at Renishaw.com/dental/LaserAbutments

QUIRYNEN, M. et al. Comparison of surface characteristics of six commercially pure titanium abutments. The International Journal of Oral & Maxillofacial Implants, 1994, 9(1), pp. 71-76.

GRÖSSNER-SCHREIBER, B et al. Plaque formation on surface modified dental implants, an in vitro study. Clinical Oral Implants Research, 2001, 12(6), pp. 543–551.

BARBOUR, M.E. et al. The effects of polishing methods on surface morphology, roughness and bacterial colonisation of titanium abutments. Journal of Materials Science: Materials in Medicine, 2007, 18(7), pp. 1439-47.

SAWASE, T. et al. Atomic force microscopic study of commercially available implant abutments. Clinical Implant Dentistry and Related Research, 1999, 1(2), pp. 92-7.

SAWASE, T. et al. Chemical and topographical surface analysis of five different implant abutments. Clinical Oral Implants Research, 2000, 11(1), pp. 44-50.

8. References

i. PHILLIPS, R.W. Skinner's science of dental materials, 8th edition. Philidelphia: W.B. Saunders Company, 1982, pp. 294-298.
ii. KRUGER, J. Electrochemistry of corrosion. In: Z. NAGY, ed. Electrochemistry encyclopedia. [Online] Available from: http://electrochem.cwru.edu/encycl/ [Accessed 17.10.2012].
iii. HJALMARSSON, L. et al. Material degradation in implant-retained cobalt-chrome and titanium frameworks. Journal of oral rehabilitation, 2011, 36, pp. 61-71.
iv. HJALMARSSON, L. On cobalt-chrome frameworks in implant dentistry [thesis]. Gothenburg, 2009, table 8, p. 43.
v. HENNING, G. Certificate – biocompatibility test [Wirobond C]. Bremen: BEGO GmbH, 21.1.2010.
vi. RENISHAW PLC, Clinical and laboratory recommendations, Incise (H-5489-8500-03-C). Wotton-under-Edge, UK, 2012.
vii. HJALMARSSON, L. et al. Implant-level prostheses in the edentulous maxilla: a comparison with conventional abutment-level prostheses after 5 years of use. The International Journal of Prosthodontics, 2011, 24(2) pp. 158-167.
viii. HJALMARSSON, ref. (iv), table 11, p. 47.
ix. HJALMARSSON, ref. (iv), table 12, p. 48.
x. QUIRYNEN, M. et al. The influence of titanium abutment surface roughness on plaque accumulation and gingivitis: short-term observations. The International Journal of Oral & Maxillofacial Implants, 1996, 11(2) pp. 169-178.
xi. Surface finish data on file (Renishaw plc, Wotton-under-Edge, UK).
xii. FEA data on file (Renishaw plc, Wotton-under-Edge, UK).
xiii. Fatigue test data on file (Renishaw plc, Wotton-under-Edge, UK).

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