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The impact of loads on standard diameter, small diameter and mini implants: a comparative laboratory study.

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Abstract: Objectives: Whilst caution in the use of small diameter ($\leq 3.5\text{mm}$) implants has been advocated in view of an increased risk of fatigue fracture under clinical loading conditions, a variety of implant designs with diameters $< 3\text{mm}$ are currently offered to the market for reconstructions including fixed restorations. There is an absence of reported laboratory studies and randomized controlled clinical trials to demonstrate clinical efficacy for implant designs with small diameters. This laboratory study aimed to provide comparative data on the mechanical performance of a number of narrow commercially marketed implants.

Materials and methods: Implants of varying designs (manufacturers: **Straumann AG**, Waldenburg, Switzerland, **Nobel Biocare AB**, Göteborg, Sweden, **Biohorizons Implant Systems Inc**, Alabama USA, **Hi Tec Implants Ltd**, Herzlia, Israel and **OsteoCare**, Slough, UK) were investigated under a standardised test set up similar to that recommended for standardized ISO laboratory testing. Implant assemblies were mounted in acrylic blocks supporting laboratory cast crowns and subjected to 30° off-axis loading on an LRX Tensometer (Lloyds Instruments Ltd, Hants, UK). Continuous output data were collected using Nexygen software (Ametek, Paoli, USA).

Results: Load/displacement curves demonstrated good grouping of samples for each design with elastic deformation up to a point of failure approximating the maximum load value for each sample. The maximum load for Straumann RN 4.1mm implant used as control was 989N ($\pm 107\text{ N}$) whereas those for Osteocare mini 2.35mm was 147N ($\pm 25\text{N}$), Osteocare mini 2.8mm 237N ($\pm 37\text{N}$) and HiTec 2.4 mm 261 N ($\pm 31\text{N}$).

Conclusions: The diameters of the commercially available implants tested had a major impact on their ability to withstand load, with those below 3mm diameter yielding results significantly below a value representing a risk of fracture in clinical practice. The results therefore support caution when considering the applicability of implants $\leq 3\text{mm}$ diameter for single tooth and FPD restorations. Standardized fatigue testing reports for commercially available implants is recommended.

Key words: Dental, implants, mini, diameter, design, overload, fatigue, fracture, failure.

Introduction

Small-diameter implants have been advocated for specific clinical situations including reduced inter-radicular bone, a thin alveolar crest, or for the replacement of teeth with small cervical diameters (Davarpanah et al 2000). Such designs may also obviate the need for bone augmentation (Barber & Seckinger 1994; Davarpanah et al 2000; Zinsli et al 2004) and preliminary orthodontic treatment (Barber & Seckinger. 1994). However, the successful use of such implants for fixed restorations are limited to a small number of clinical reports of limited numbers of implants (Polizzi et al 1999; Romeo et al. 2004; Vigolo et al 2004; Zinsli et al. 2004; Romeo et al. 2006). Some of these reports include incidences of implant fractures (Romeo et al. 2004; Zinsli et al. 2004). Fractures have also been reported following the clinical use of well-documented implant designs (Adell et al. 1981; Morgan et al. 1993; Rangert et al. 1995; Eckert et al. 2000). Indeed, one recent systematic review reported that implant fractures constitute between 5-20% of all implants lost during function (Berglundh et al. 2002). Various workers have previously highlighted the risk of fatigue fracture of smaller diameter implants, especially in areas of high loading (Rangert et al. 1995; Polizzi et al. 1999; Renouard & Rangert 1999; Eckert et al. 2000; Zinsli et al. 2004). Furthermore, FE analysis has shown small-diameter implants to adversely affect loading conditions on crestal bone (Petrie & Williams. 2005). This is of particular importance as loss of crestal bone could be detrimental to loading conditions by increasing the lever-arm effect and bending moments on the implant.

Although caution has been advocated when using implants with diameters of less than 3.5 mm (Rangert et al. 1995; Renouard & Rangert 1999; Davarpanah et al 2000; Zinsli et al. 2004), a number of newer implant designs with diameters below 3.0mm have recently been introduced to the market under the banner of “mini implants”, some incorporating abutment designs intended for the support of fixed restorations. Aside from reports on a now

discontinued two-part design (Vigolo & Givani 2000; Vigolo et al. 2004), publications specifically documenting experiences with the use of “mini implants” are extremely limited, often reporting clinical application for temporary support only (Zubery et al. 1999; Balkin et al. 2001; Krennmair et al. 2003; Leshem et al. 2003).

Cyclic loading tests mimicking years of functional use should ideally be used to test implant designs (Bragger 1999). However, despite the publication of recommended international standards for fatigue testing (ISO 14801; 2003), this basic information remains largely unavailable to practitioners since it is not freely published by manufacturers.

Although fatigue testing is the most appropriate test design to produce data of clinical relevance, a simple overload test can also be used to produce relevant data, since general engineering principles stipulate that fatigue failures obey mechanical laws which correlate with the dimensions of the material itself and its inherent mechanical properties (von Recuum 1986; Plenk & Zitter 1996). For both titanium and titanium alloys used in implant manufacture, the fatigue limit and the ultimate tensile strength are closely related. Repeated application of forces approximating 50% of the material’s ultimate tensile strength under direct tension-compression will attain this fatigue limit with catastrophic fracture after an estimated 10^7 load cycles (Forest 1962; Lemons & Dietsch-Misch 1999; ISO 14801. 2003; IMI Titanium 2005). This relationship has been demonstrated previously in a laboratory investigation of implants subjected to both fatigue and simple overload testing (Huang et al. 2005). Since it has been estimated that an average individual makes approximately 10^6 chewing cycles per year (Wiskott et al. 1995), an implant exposed to bite forces approximating 50% of its ultimate tensile strength might be expected to endure about 10

years' clinical use. Against this background, the authors have devised a simple overload test based around the ISO recommendations (ISO 14801, 2003), to produce basic comparative data to help estimate the relative mechanical performance of implants which might be expected in situ when used to support fixed single units.

The aim of this study, therefore, was to use an overload test on a number of commercially available standard and mini-implant systems to compare loads at failure.

Materials and Methods

Eight commercially available implant designs (Table 1) were subjected to laboratory analysis with a test set-up similar to that prescribed by ISO 14801(2003). Ten samples of each of the eight designs were embedded vertically in acrylic blocks (*Excel Heat Cure Denture Acrylic, Wright Health Group Ltd, Dundee, Scotland*) in a manner simulating 3mm of crestal bone loss.

Each test implant supported a 5mm diameter cylindrical crown cast in Cobalt Chromium alloy which seated onto the unmodified abutment. Test crowns extended apically onto manufacturer's pre-machined finishing lines where these existed. The height from the occlusal surface of each test crown to the level of the embedding acrylic supporting the implant was standardized at 14mm. The acrylic blocks carrying implant/abutment/crown assemblies were subsequently loaded into a steel cradle (Fig 1) designed to securely position each sample at an angle of 30° from the vertical (ISO 14801 2003).

Testing was performed using a Lloyds LRX Tensometer (Lloyds Instruments Ltd, Hants, UK - Fig 2). A schematic of the test set-up is shown in Fig 3. A small preload (0.5N) was applied to each test sample to ensure that all components and acrylic blocks were fully settled before each test was started.

Off-axis loading was applied to each implant assembly via the vertical piston of the Tensometer, which descended at a continuous speed of 1mm/min until the piston achieved a maximum travel of 6mm. This displacement parameter was set following initial piloting of the Straumann implant designs and to ensure that data were recorded beyond the point of yield under maximum load for each test sample. Although it transpired that for some designs the test end-point did not conclude with a fractured implant (i.e. some tests ended with a bent implant), this outcome did not form part of the current investigation.

Continuous output data of the applied load and distance traveled by the piston were collected in real time with Nexygen software (Ametek, Paoli, USA). Data were subsequently processed and analysed using Microsoft Excel 2000 and Epi Info™ software (CDCP, Atlanta, Georgia, USA). Load/displacement curves characteristic for each implant design were generated and mean maximum loads, maximum bending moments and their appropriate standard deviations were calculated.

Results

Only 9 samples of the Straumann 3.3mm NN Implant, the NobelDirect™ 3.0 Implant, and the Hi Tec TRI-N-13 Implant were tested as prescribed. This was due to faulty mounting in the steel cradle, laboratory error during mounting and supply of an incorrect design due to manufacturer's packaging fault respectively. Load/displacement curves demonstrated good

grouping of all test samples for individual implant designs, reinforcing the validity of the test set-up. Examples of curves for samples of two of the designs are shown in Figs 4 and 5. Curves for all designs showed elastic deformation up to a point of failure which closely approximated the maximum load value for the test sample. Shortly after achieving the maximum load value, the load/ displacement curves of each test sample entered a failure phase. For some implant designs, the curve of this failure phase concluded with a sharp drop to a load value of zero indicating complete fracture of the test implant (Fig 4). However, for other designs the test concluded before complete collapse of the test sample when the piston reached 6mm of displacement, concluding with a bent implant still capable of supporting a reduced load value (Fig 5). Since displacement of the samples under load were also recorded, maximum bending moments could also be calculated for each implant design. Test results for all implant designs are summarized in Table 2 and also in Figs 6 and 7.

For the purposes of statistical analysis, the non-parametric Wilcoxon test was applied to test the differentials in the mean maximum load values for all pairs of implant designs. Statistical analysis of the results indicated no significant difference between the performance of the Straumann 3.3mm NN implant and the Maximus 3.0™ implant ($p=0.25$), nor between that of the Osteocare 2.8mm Mini implant and the Hi Tec TRI-N-13 implant ($p=0.14$). For all other pairs of designs significant differences were found ($p<0.02$). The two Straumann 3.3mm diameter designs produced significantly different outcomes for implants with identical endosseous sections, but differing abutment connections ($p=0.0008$) (see Table 2).

Discussion

The Straumann 4.1mm solid screw RN Implant is a well documented design which has been in use since 1985 (Scacchi et al 2000) and does not appear prone to fracture (Buser et al. 1997). Consistent with a previous report (Cehreli et al. 2004), no incidences of fracture of this particular design appear to have been reported in the literature. The values attained in the current study for this design may therefore be taken to represent a load resistance representing complete safety in clinical practice.

The Straumann 3.3mm RN implant (which has the same abutment connection and platform as the Straumann 4.1mm implant but a reduced endosseous diameter) has also been in use for over 20 years (Scacchi et al 2000). However, only 2 studies were identified in the literature from which limited data could be obtained for this design. A 10-year prospective study of 298 consecutively placed Straumann 3.3mm RN implant concluded that this implant had the potential to perform successfully over significant periods when clinical protocols were carefully followed (Zinsli et al. 2004). However, only 67 implants were used to support fixed restorations and of these 2 fractures (3%) were reported. Romeo et al (2004) also experienced 2/22 fractures (9%) with this design but no fractures of 105 3.3mm NN design implants (Romeo 2006b).

For all other implant designs tested in the study, clinical data does not appear to be available. Therefore the laboratory results can only be evaluated subjectively against clinical reports of the Straumann 4.1mm RN implant and the Straumann 3.3mm RN implant.

Results obtained with the Straumann Ø3.3mm NN and the Straumann 3.3mm RN implant assemblies indicate that the design of the abutment connection and the associated assembly can influence the ability of the structure to withstand load (these implants feature identical external endosseous sections and are manufactured in the same material). It seems likely that the integral abutment design was a factor that contributed to the fact that both the Maximus 3.0™ Implant and the NobelDirect™ 3.0 Implant out-performed the wider Straumann Ø3.3mm RN implant. However, the fact that implants were manufactured in different materials must also be considered (see Table 1). Titanium alloy (Ti-6Al-4V) demonstrates better tensile properties than Grade 4 CP titanium, which in turn out-performs lower grades of CP titanium (Williams 1977; Misch 1999; IMI Titanium 2005).

Although test outcomes for the Straumann Ø3.3mm NN, the Maximus 3.0™ and the NobelDirect™ 3.0 suggest the possibility of increased fracture resistance for these designs in comparison to the Straumann Ø3.3mm RN implant, the results for all these designs fell significantly short of the values attained by the Straumann 4.1mm RN Implant. At present, the lack of clinical and other data means that it is not possible to estimate the effect on clinical performance.

Data obtained for the implant samples with diameters below 3mm showed maximum load values well below that attained by the Straumann Ø3.3mm RN implant. These differences were statistically significant. The authors believe the scale of these differences strongly suggest that the risk of fracture for these designs could be clinically significant.

With regard to the clinical environment, it is important to remember that higher load values are sustained by posterior teeth compared with their more anterior counterparts (Brunski et

al. 2000). Functional loads of approximately 100N have been noted for incisors, increasing monotonically along the arch to a value approaching 300N in the molar region (Ferrario et al. 2004). However, values of 300N have been suggested as an appropriate load value for single premolar implants (Eskitascioglu et al. 2004) and maximum bite forces as high as 700N have been suggested in the second molar region of the natural dentition (van Eijden 1991). These values are certainly within range of 50% of the maximum load values of many of the test samples used in the current study suggesting a risk of fatigue fracture for some of these implants if used inappropriately.

Some attempt was made to standardize the length of implants involved in the investigation at around 14mm. However, there was some variation with lengths of implant designs varying from 12-15mm (Table 1). Whilst the current study has focused on the diameter of commercially available implant designs, Petrie et al recently highlighted the fact that length, diameter and taper are inter-related (Petrie & Williams. 2005). The possibility of varying outcomes with different length implants must therefore be considered, particularly for implants with a tapered design.

Conclusion

This study showed that implants with diameters below 3mm yielded results which were significantly below those of a larger diameter. Given the lack of clinical data for mini-implants, this suggests that caution advised when considering these implants for single tooth and/or FPD restorations may be justified.

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Fig1: Each implant/crown assembly was mounted in an acrylic block which was itself secured in the cradle of the steel mounting block. This set-up held each implant with axis off-set 30° from the vertical (as per ISO 14801; 2003).



Fig 2: Mounted samples on the steel block were positioned under the vertical ram of the Tensometer (Lloyds Instruments Ltd, Hants, UK). With the ram traveling at 1mm/Min, continuous output data recorded the load applied and distance traveled by the ram.

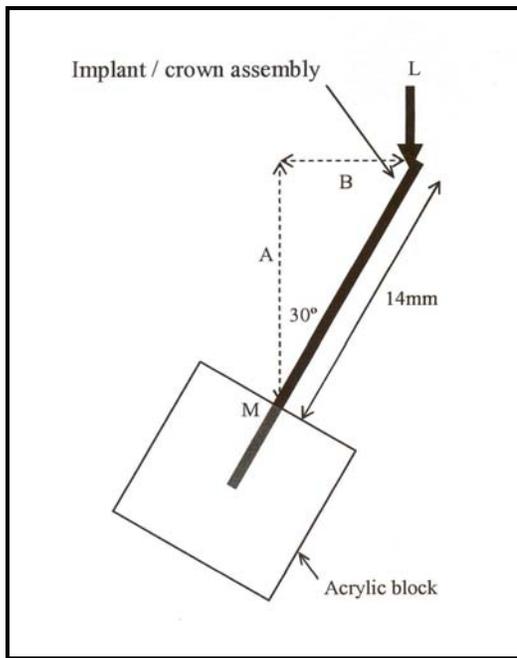


Fig 3: Schematic of test set-up.

L = Load applied via the tensometer ram.

A = Vertical height of tensometer ram. During the test, this distance reduces by a value D, the vertical displacement of the tensometer ram.

B = Horizontal offset of the tensometer ram. This value increases as the test proceeds.

M = point at which bending moments are applied to the implant.

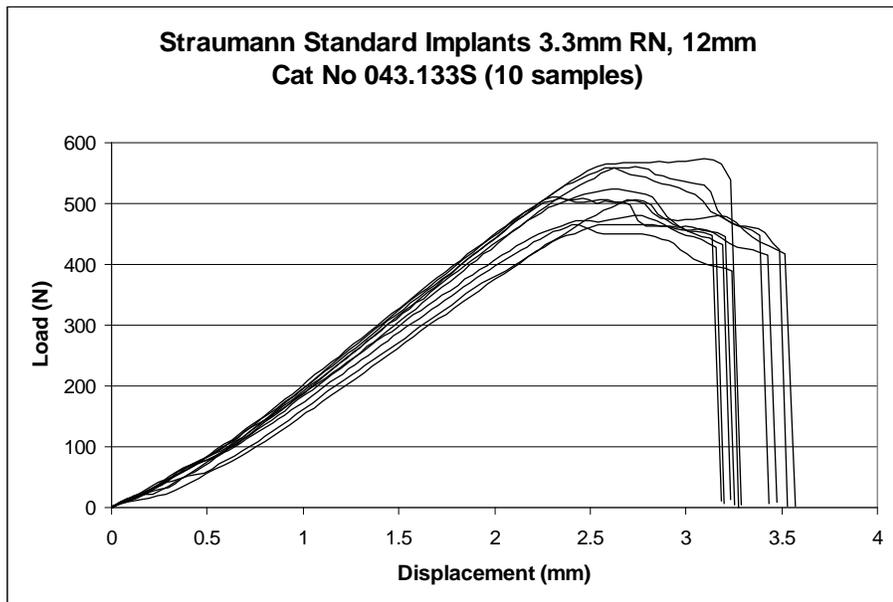


Fig 4: Load /vertical displacement curves for the Straumann 3.3mm RN test implants. As for all other designs, the curves showed good grouping, demonstrating elastic displacement up to a point approximating the maximum sustained load. After this point, following further application of load, the load value was seen drop sharply to zero as each sample completely fractured.

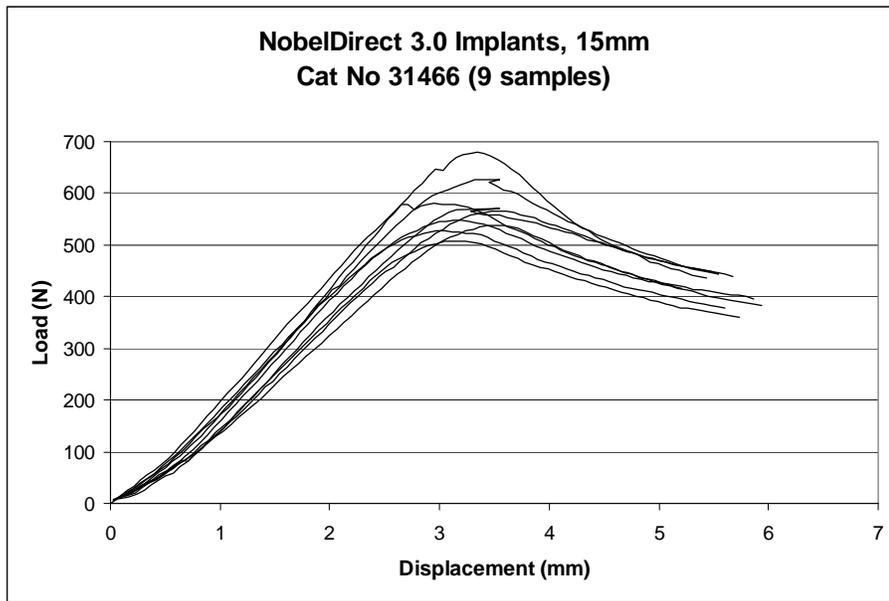


Fig 5. Load /vertical displacement curves for the NobelDirect™ 3.0 Implant. Curves peaked at a Maximum load value and subsequently entered a failure phase. However these curves did not drop to zero before the piston travel of 6mm was completed – ie samples were bent but did not completely fracture. Whether they would have fractured under greater displacement is open to speculation - however this outcome did not form part of the current test.

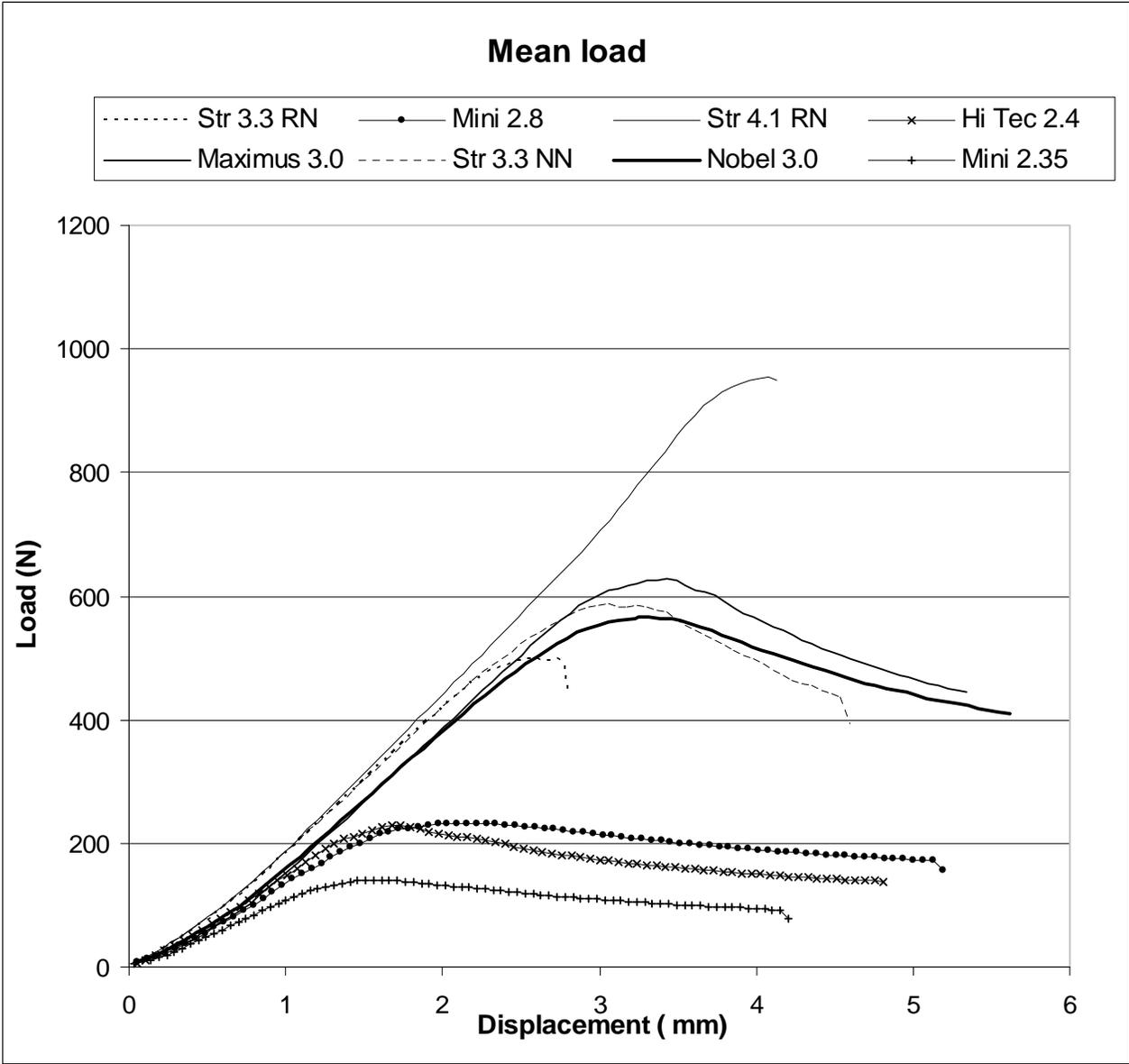


Fig 6: Load displacement curves for each design tested generated from mean values.

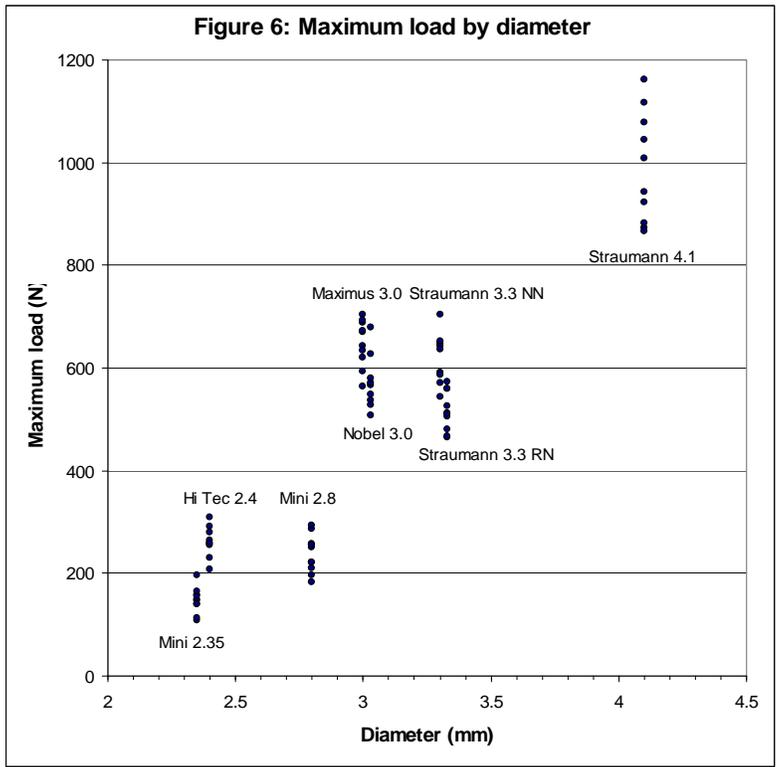


Fig 7: Summary of results for all samples

<i>Test lot</i>	<i>Manufacturer</i>	<i>Implant</i>	<i>Catalogue No</i>	<i>Material</i>	<i>Abutment</i>	<i>Catalogue No</i>
1	StraumannAG CH-4437 Waldenburg, Switzerland	Standard Implant Ø 4.1mm RN SLA 12mm	043.033S	Grade 4 CP Titanium Cold-Worked	RN Solid Abutment 6° Ht 7.0 mm	048.542
2	StraumannAG CH-4437 Waldenburg, Switzerland	Standard Implant Ø 3.3mm RN SLA 12mm	043.133S	Grade 4 CP Titanium Cold-Worked	RN Solid Abutment 6° Ht 7.0 mm	048.542
3	StraumannAG CH-4437 Waldenburg, Switzerland	Standard Plus Implant Ø 3.3mm NN SLA 12mm	042.932S	Grade 4 CP Titanium Cold-Worked	NN Titanium Post NN Occlusal screw	048.505 049.177
4	OsteoCare	Mini Implant Post Type Ø2.8mm / 13mm	IM-MNP280- 130	Ti-6Al-4V	N/A (Integral Design)	N/A (Integral Design)
5	OsteoCare	Mini Implant Post Type Ø2.35 / 13mm	IM-MNP235- 130	Ti-6Al-4V	N/A (Integral Design)	N/A (Integral Design)
6	Hi-Tec Implants LTD PO Box 2022 Herzlia, Israel	cementable abutment type, Ø 2.4mm/ 13mm	TRI-N-13	Ti-6Al-4V	N/A (Integral Design)	N/A (Integral Design)
7	Nobel Biocare AB Göteborg, Sweden	NobelDirect™ 3.0 15mm	31466	Grade 4 CP Titanium	N/A (Integral Design)	N/A (Integral Design)
8	Biohorizons Implant Systems Inc. South Birmingham Alabama AL 35243	Maximus 3.0™ 15mm	3015D3	Ti-6Al-4V	N/A (Integral Design)	N/A (Integral Design)

Table 1: Implants and components used in the current study. Where implants did not feature an integral abutment, standard cementable abutments were used (as listed) and assembled according to the manufacturers' instructions.

<i>Implant Type / diameter</i>	<i>Maximum Loads</i> <i>Means (+/- standard deviations)</i>	<i>Maximum bending moments</i> <i>Means (+/- standard deviations)</i>
<i>Straumann RN / 4.1mm</i>	989N (+/- 107N)	11558Nmm (+/- 1251Nmm)
<i>Straumann NN / 3.3mm</i>	619N (+/- 50N)	6992Nmm (+/- 1317Nmm)
<i>Straumann RN/ 3.3mm</i>	515N (+/- 39N)	5311Nmm (+/- 455Nmm)
<i>NobelDirect™ / 3.0mm</i>	572N (+/- 53N)	5598Nmm (+/- 623Nmm)
<i>Maximus™ / 3.0mm</i>	648N (+/- 45N)	7050Nmm (+/- 560Nmm)
<i>Osteocare Mini /2.8mm</i>	237N (+/- 37N)	2319Nmm (+/- 411Nmm)
<i>Hi Tec / 2.4mm</i>	261N (+/- 31N)	2251Nmm (+/- 297Nmm)
<i>Osteocare Mini /2.35mm</i>	147N (+/- 25N)	1350Nmm (+/- 224Nmm)

Table 2: Maximum loads sustained and the maximum bending moments recorded for each implant design.