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Mechanical Behavior and Failure Analysis of Prosthetic Retaining Screws after Long-term Use In Vivo. Part 3: Preload and Tensile Fracture Load Testing

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Mechanical Behavior and Failure Analysis of Prosthetic Retaining Screws after Long-

term Use In Vivo. Part 3: Preload and Tensile Fracture Load Testing

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Abstract

Purpose: The aim of this study was to determine the preload and tensile fracture load values of prosthetic retaining screws after long-term use in vivo compared to unused screws (controls). Additionally, the investigation addressed whether the preload and fracture load values of prosthetic retaining screws reported by the manufacturer become altered after long-term use in vivo.

Materials and Methods: For preload testing, 10 new screws (controls) from Nobel Biocare (NB) and 73 used retaining screws [58 from NB and 15 from Sterngold (SG)] were subjected to preload testing. For tensile testing, eight controls from NB and 58 used retaining screws (46 from NB and 12 from SG) were subjected to tensile testing. Used screws for both tests were in service for 18–120 months. A custom load frame, load cell, and torque wrench setup were used for preload testing. All 83 prosthetic screws were torqued once to 10 Ncm, and the produced preload value was recorded (N) using an X–Y plotter. Tensile testing was performed on a universal testing machine and the resulting tensile fracture load value was recorded (N). Preload and tensile fracture load values were analyzed with 2-way ANOVA and Tukey post-hoc tests.

Results: There was a significant difference between preload values for screws from NB and screws from SG ($p < 0.001$). The preload values for gold alloy screws from NB decreased as the number of years in service increased. There was a significant difference between tensile fracture values for the three groups (gold alloy screws from NB and SG and palladium alloy screws from NB) at $p < 0.001$. The tensile fracture values for gold alloy screws from NB and SG decreased as the number of years in service increased.

Conclusions: In fixed detachable hybrid prostheses, perhaps as a result of galling, the intended preload values of prosthetic retaining screws may decrease with increased in-service time. The reduction of the

fracture load value may be related to the increase of in-service time; however, the actual determination of this relationship is not possible from this study alone.

As a fail-safe mechanism to protect the implant and prosthesis, retaining screws are made as the weakest-link prosthetic components in fixed detachable hybrid prosthesis design.[1, 2] With optimal preload and tensile strength of retaining screws, the prosthetic components become more resistant to loosening and/or fracture.[3, 4] The optimal preload value remains unknown.[4] Similarly, optimal tensile strength remains unknown. It is true that higher torque leads to higher preload, and higher preload leads to greater clamping force, but the force must be within the elastic limit of the retaining screws when preload is applied.[5, 6] In fastener mechanics, the recommended preload value is 75% of yield strength.[6, 7] Several in vitro studies have been performed on the ultimate tensile strength of retaining screws.[4, 8, 9] Data indicated differences in ultimate tensile strength of prosthetic retaining screws made by the same manufacturer and by different manufacturers, suggesting variation in component specifications.

A recent in vitro study evaluated the effect of repeated torque on the preload value of retaining screws and reported that higher preload was achieved after repeated use of retaining screws.[7] The reasons that the torque value required to provide a given preload for a used screw is less than that for a new screw are unknown, as is the exact quantitative difference. It is not known whether the ultimate tensile strength of the used screw decreases as in-service time increases, although there is no reason to think it would. To date, the effect of the increase of in-service time on the preload and ultimate tensile strength values of retaining screws remains unknown.

The aim of this study was to determine the preload and tensile fracture load values of prosthetic retaining screws after long-term use in vivo compared to unused screws (controls). Additionally, the investigation addressed whether the preload and fracture load values of prosthetic retaining screws reported by the manufacturer become altered after long-term use in vivo.

Materials and methods

One hundred (10 new and 90 used) prosthetic retaining screws were tested. The ten new screws (controls) were from Nobel Biocare (NB) (Göteborg, Sweden), and the 90 used screws [in service 18–120 months; 60 from NB and 30 from Sterngold (SG) (Attleboro, MA)] were collected from 18 patients (5 screws from each patient) and divided into 18 groups. For more detail regarding the group classification system, screw type, screw manufacturers, and detailed in - service history, refer to Part 1 of this series.

Preload testing

Only 83 retaining screws out of 100 were subjected to preload testing, because: (1) most of the 15 retaining screws in Groups 16, 17, and 20 were fractured in two pieces at retrieval and, therefore, excluded from testing; and (2) the two retrieved conical retaining screws in Groups 5 and 18 were excluded from statistical analysis. The purpose of this testing was to evaluate the effect of long-term use of implant prosthetic retaining screws in vivo on the torque/preload relationship. All 83 prosthetic screws were subjected to preload testing according to an accepted protocol (Fig 1).[7]

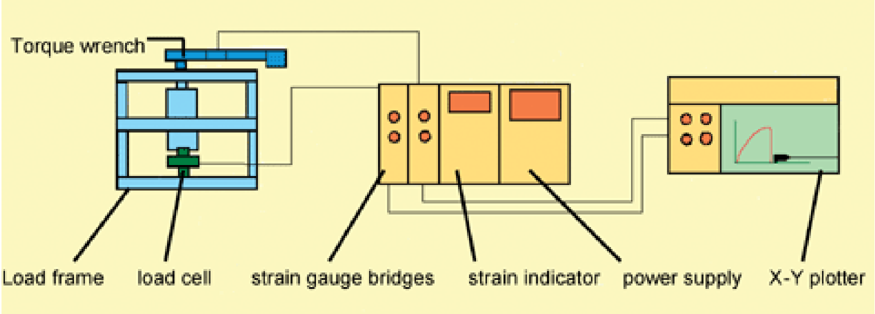

Figure 1 Torque/preload test setup.

A heat-treated stainless steel custom load frame containing bottom, middle, and horizontal plates and a load cell (ELF TC 13–250, Entran Devices Inc, Fairfield, NJ) were used for positioning and holding the implant component stack. The implant stack consisted of: (1) implant fixture (II310, 3i Implant Innovations Inc, West Palm Beach, FL); (2) standard 3 mm abutment and abutment screw (AB400 and AB400S, 3i Implant Innovations Inc); and (3) a standard gold cylinder (SGC30, 3i Implant Innovations Inc). The custom metal frame ensured that its centerline was coincident with the loading axis during testing.

The prosthetic screws were torqued once to 10 Ncm using a custom-made torque wrench. The torque wrench was designed and machined to accept and secure the manufacturer prosthetic screwdriver (DIB 048, Nobel Biocare USA, Yorba Linda, CA). Before torquing, the load cell and the torque wrench were calibrated using known loads to give accurate and repeatable recordings. Screw torquing was delivered in a steady manner by stabilizing and holding the head of the screw wrench vertically with one hand while the other hand applied the torquing force to the end of the wrench arm. During torquing, a pen on graph paper was observed until it reached the required torque value. The produced preload resulting from 10 Ncm torque was then recorded (N) using an X–Y plotter.

Tensile testing

Only 66 prosthetic retaining screws out of 83 previously tested screws were subjected to tensile testing, because one screw from each test group was used for metallographic and microhardness testing in Part 2 of this series.

The purpose of tensile testing was to determine the fracture load required to break the prosthetic retaining screws. An Instron universal testing machine (Instron Corporation, Canton, MA) was used for tensile testing, and a previously designed specimen-holding fixture was used to ensure a central loading axis.[8] The loading fixture consisted of: (1) a standard gold cylinder (SGC30) to support the head of the gold screw; (2) a hardened steel collar housing the gold cylinder (9 mm in diameter, 4.5 mm in height); 3) a hardened steel plate (2 mm thick, 25 mm wide, and 115 mm long) with a center hole (5.5 mm in diameter) to support the hardened steel collar, and a two-sided hole for the attachment of the eye and U bolt with lock nuts; (4) the eye and U bolts attached to the upper grip of the Instron machine; and (5) a stainless steel wire loop (0.045 inch in diameter) passed through a transverse hole made on the abutment replica (DCA 175, Nobel Biocare) used to secure the lower part of the holding fixture to the lower grip of the Instron machine.

For tensile testing, as previously described[8] and as shown in Figure 2, the upper grip of the specimen holding fixture was attached to the tensile load cell, and the wire loop around the abutment replica was attached to the lower crosshead grip of the Instron. Using a screwdriver, the prosthetic screw was tightened until first resistance and then backed off one quarter of a turn. To determine the tensile fracture load value, a 0.5 mm/min crosshead speed on the Instron and a load cell with a scale range of 1000 lbs were used. The tensile fracture load values of tensile testing were recorded (N), and the tensile fracture load was considered to have been reached when a sudden drop in load to zero was noted.

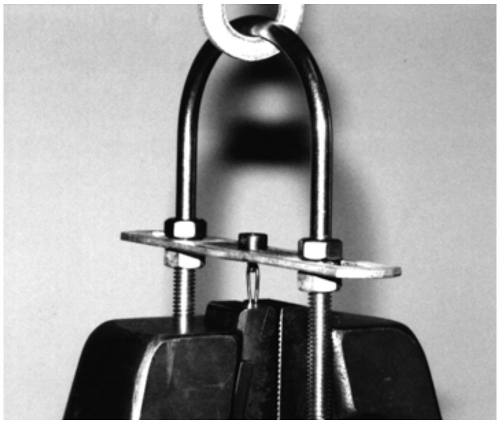

Figure 2 Custom specimen holding fixture mounted in the Instron Machine.

Results

Torque preload testing

The results of mean preload values and basic descriptive statistics of each tested group are presented in Table 1 and shown graphically in Figure 3. Additional statistical analysis was performed to determine: (1) the effect of alloy type (determined by EDX analysis in Part 2 of this series) on preload values; and (2) the effect of time period of in-service life on preload values.

Table 1. Mean and basic descriptive statistics of preload values (P) in newtons for each prosthetic screw group at a torque of 10 Ncm

Group number	**No. of spec.**	**Preload values (P) in Newton**				**S.E MEAN**	**STD. DEV.**
		F_{MIN}	**F_{MAX}**	**F_{MEAN}**	**F_{MEDIAN}**		
1	5	198.0	213.0	**207.0**	208.0	2.8	6.2
2	5	204.0	220.0	**209.4**	208.0	2.9	6.4
3	5	116.0	156.0	**136.8**	141.0	7.5	16.8
4	5	160.0	186.0	**168.4**	164.0	4.7	10.5
5	4	158.0	174.0	**168.5**	171.0	3.6	7.2
6	5	145.0	188.0	**166.6**	165.0	7.2	16.1
7	5	138.0	186.0	**155.6**	152.0	8.3	18.6
8	5	192.0	230.0	**213.6**	214.0	6.4	14.3
9	5	180.0	198.0	**188.0**	190.0	3.2	7.2
10	5	132.0	158.0	**147.2**	148.0	4.8	10.6
11	5	142.0	170.0	**157.6**	156.0	5.2	11.6
12	5	240.0	334.0	**269.6**	260.0	16.8	37.7

Group number	No. of spec.	Preload values (P) in Newton				S.E MEAN	STD. DEV.
		F_{MIN}	F_{MAX}	F_{MEAN}	F_{MEDIAN}		
13	5	218.0	272.0	**243.8**	236.0	10.9	24.4
14	5	260.0	300.0	**277.2**	270.0	7.6	17.0
15	5	154.0	190.0	**172.8**	176.0	7.3	16.2
16	NA	-	-	**-**	-	-	-
17	NA	-	-	**-**	-	-	-
18	4	196.0	220.0	**207.5**	207.0	5.1	10.1
19	5	140.0	162.0	**150.8**	150.0	3.8	8.6
20	NA	-	-	**-**	-	-	-

Note that the number of the screws in Groups 5 and 18 is four because preload values of the two retrieved conical screws were not included in statistical calculations.
NA = Not applicable, because some screws were fractured at retrieval.

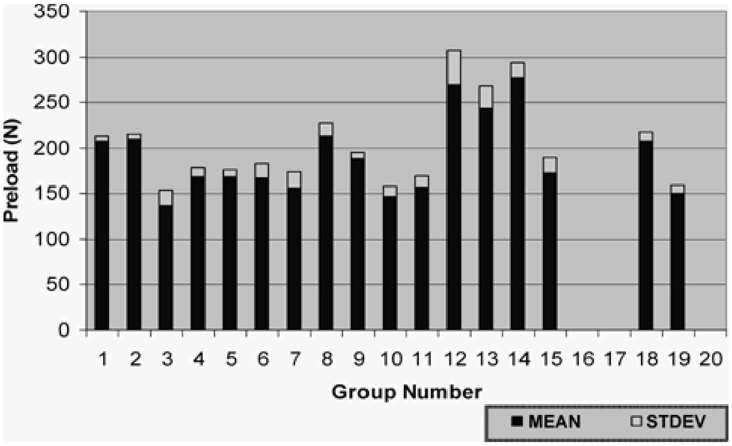

Figure 3 The mean preload values and standard deviation for prosthetic retaining screws at a torque of 10 Ncm.

To determine the effect of the alloy type on the preload values, screws were categorized into three groups (Group 1, gold alloy screws from NB; Group 2, palladium alloy screws from NB; and Group 3, gold alloy screws from SG). Table 2 shows the number of screws in each group. Similarly, to determine the effect of time period of in-service life on preload values, screws were categorized into four groups (Group 0, control screws which had 0 months in-service time; Group 1, screws that had more than 0 and < 30 months in-service time; Group 2, screws that had more than 30 and ≤ 60 months in-service time; and Group 3, screws that had more than 60 months of in-service time). Table 3 shows the number of screws in each group.

Table 2. Total number of prosthetic screws in each classified group based on alloy type

Alloy type group number	Alloy composition	Number of screws
1	Gold alloy from NB	58

Alloy type group number	Alloy composition	Number of screws
2	Palladium alloy from NB	10
3	Gold alloy from SG	15

Table 3. Total number of prosthetic screws in each classified group based on time period of in-service life

In-service time group number	Number of months in service	Number of screws
0	0	10
1	0 < in service life ≤ 30	34
2	30 < in service life ≤ 60	24
3	60 < in service life	15

The results of mean preload values and basic descriptive statistics for both groups are presented in Table 4 and graphically represented in Figure 4. Two-way analysis of variance (ANOVA) and post-hoc Tukey statistical analysis tests were used to determine if there was any statistically significant difference in the mean preload values shown in Figure 5 for the three groups classified by alloy composition. There was a significant difference between preload values for gold alloy screws from NB and gold alloy screws from SG ($p < 0.001$) (Table 5). There was a similar significant difference between preload values for palladium alloy screws from NB and gold alloy screws from SG. There was no statistical difference between preload values for gold alloy and palladium alloy screws from NB at $p < 0.05$.

Table 4. Mean and basic descriptive statistics of preload values for prosthetic screw groups classified by alloy composition and in-service time

Alloy type group number	In-Service time group number	No. of spec.	Mean	Std. Dev.	95% Confidence interval
1	0	10	208.2	6.0	193–223
	1	24	162.3	15.2	152–172
	2	19	176.8	36.8	165–187
	3	5	188.0	7.2	166–209
2	3	10	159.6	12.9	144–174
3	1	10	260.5	26.5	245–275
	2	5	269.6	37.7	248–291

Entries are mean value ± standard deviation in Newtons.

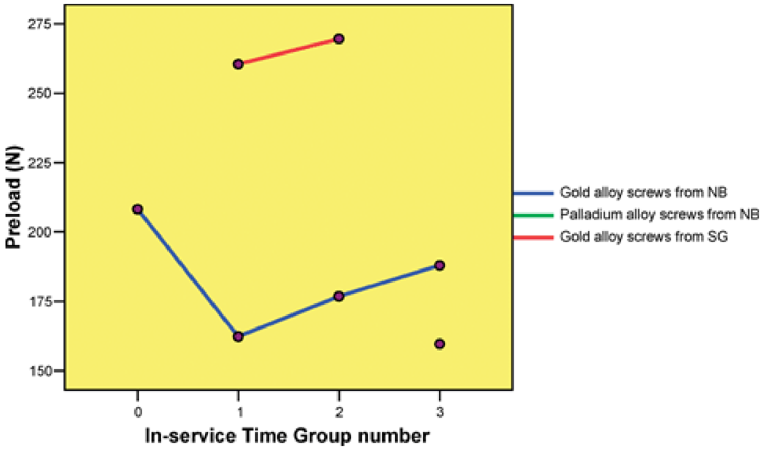

Figure 4

Mean preload values for the three prosthetic screw groups with different alloy compositions. Additionally, the effect of in-service time on the mean preload values is shown for each group.

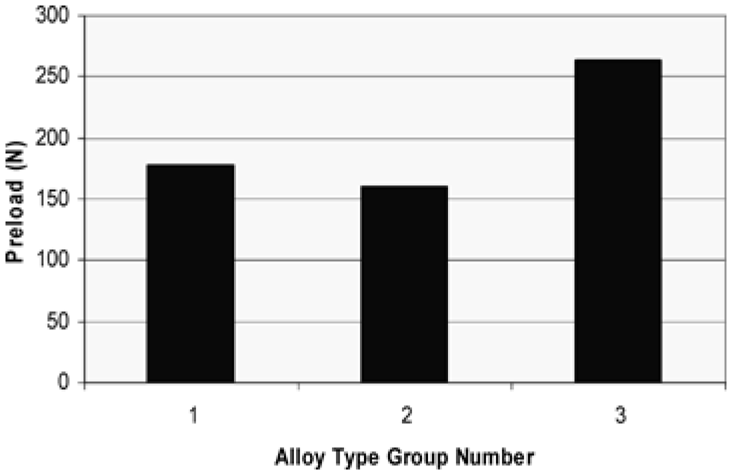

Figure 5

Mean preload values for the three prosthetic screw groups classified by alloy type (composition). 1 = Gold alloy screw from NB, 2 = Palladium alloy from NB, 3 = Gold alloy screw from SG.

Table 5. Tukey multiple range test I (*p* < 0.001)

Group number based on alloy composition (see Table 2)	Mean preload value (N)
1	177.19^{a}
2	159.6 ^{a}
3	263.53^{b}

Values with same superscript letters are not significantly different.

With the increase of in-service time, the mean preload values for gold alloy screws from NB decreased from Group 0 to 1, then started to increase from Group 1 to 3 (Fig 4). Post-hoc statistical testing demonstrated a significant difference between preload values for Group 0 and Group 1 at $p < 0.001$, and a significant difference for Group 0 and Group 2 at $P < .01$. There was no statistically significant difference between other groups at $p < 0.05$. Additionally, for palladium alloy screws from NB and gold alloy screws from SG, post-hoc analysis demonstrated no statistically significant difference between preload values within each group at $p < 0.05$.

Fracture load testing

The mean fracture load values and basic descriptive statistics for each tested group are presented in Table 6 and graphically shown in Figure 6. To determine the effect of the alloy type and the time period of in-service life on the mean fracture load values, methods very similar to those used for preload testing for the previously mentioned group classifications and statistical analysis were followed. Table 7 shows the number of screws in each group classified by alloy composition, and Table 8 shows the number of screws in each group classified by the time period of in-service life.

Table 6. Mean and basic descriptive statistics of fracture load values (F) in newtons for each prosthetic screw group

Group number	**No. of spec.**	**Fracture load values (F)**				**S.E MEAN**	**STD. DEV.**
		F_{MIN}	**F_{MAX}**	**F_{MEAN}**	**F_{MEDIAN}**		
1	4	923.0	940.2	**930.7**	929.7	4.3	8.7
2	4	913.7	940.2	**924.5**	922.1	5.9	11.9
3	4	825.5	863.3	**844.0**	843.5	8.7	17.3
4	4	972.9	1133.6	**1037.3**	1021.3	35.7	71.3
5	3	700.0	706.0	**703.6**	704.7	1.8	3.2
6	4	764.2	844.0	**810.1**	816.1	20.1	40.1
7	4	697.8	706.0	**702.1**	702.4	1.9	3.9
8	4	775.0	809.0	**790.5**	789.0	9.0	18.0
9	4	784.2	860.8	**825.7**	829.0	18.4	36.7
10	4	792.7	868.6	**842.8**	855.1	17.0	34.0
11	4	799.5	819.1	**810.3**	811.2	4.3	8.3
12	4	725.0	745.6	**733.5**	731.8	4.5	9.0
13	4	720.5	754.7	**734.7**	731.8	7.2	14.5
14	4	724.9	758.0	**744.6**	747.7	7.7	15.4
15	4	817.5	849.4	**831.4**	829.4	6.6	13.3
16	NA	-	-	**-**	-	-	-
17	NA	-	-	**-**	-	-	-
18	3	697.9	751.0	**723.4**	721.4	15.4	26.6
19	4	845.2	1013.5	**929.5**	929.7	42.2	84.4
20	NA	-	-	**-**	-	-	-

Note the number of the screws in Groups 5 and 18 is three, because preload values from the two retrieved conical screws were not included in statistical calculations.
NA = Not Applicable. Some screws were fracture at retrieval.

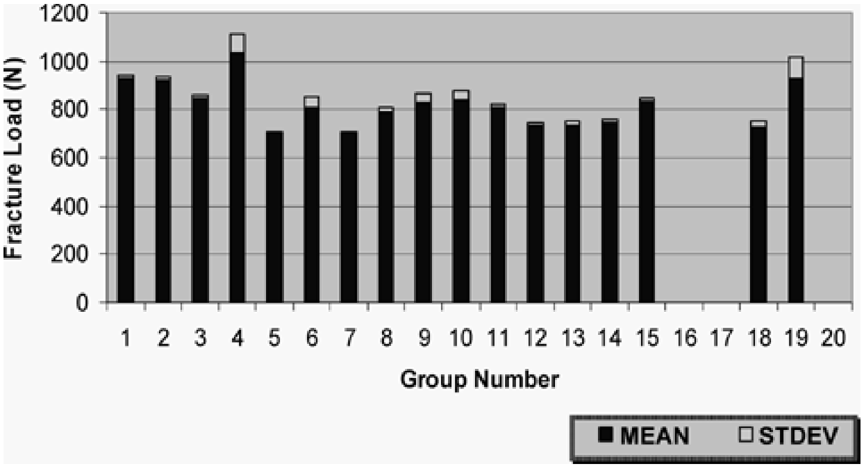

Figure 6
Mean preload values and standard deviations for each prosthetic screw group.

Table 7. Total number of screws in each group based on alloy type

Alloy type group number	Alloy composition	Number of screws
1	Gold alloy from NB	46
2	Palladium alloy from NB	8
3	Gold alloy from SG	12

Table 8. Total number of screws in each group based on number of months in service

In-service time group number	Number of months in service	Number of screws
0	0	8
1	0 < in service life ≤ 30	27
2	30 < in service life ≤ 60	19
3	60 < in service life	12

The results for mean fracture load values and basic descriptive statistics for both groups are presented in Table 9 and graphically shown in Figure 7. Two-way ANOVA and post-hoc Tukey statistical analysis tests were used to determine if there was any statistically significant difference in the mean fracture load values shown in Figure 8 for the three groups classified by the alloy composition. There was a significant difference between fracture values for the three groups at $p < 0.001$ (Table 10). As can be seen in Figure 7, the mean fracture load values for gold alloy screws from NB decreased as in-service time increased. Post-hoc statistical testing demonstrated a statistically significant difference between fracture load values for Group 0 and Groups 1 and 2 at $p < 0.001$, and a significant difference for Group 0 and Group 3 at $p < 0.05$. There was no statistically significant difference between other groups at $p < 0.05$. Similarly, the mean fracture load values for gold alloy screws from SG decreased as in-service time increased. Post-hoc testing demonstrated no statistically significant difference between fracture load values at $p < 0.05$.

Table 9. Mean and basic descriptive statistics of fracture load values for prosthetic screw groups classified by alloy composition and in-service time

Group number based alloy composition	Group number based on in-service time	no of spec.	Mean	Std. Dev.	95% confidence interval
1	0	8	927.6	10.2	900–965
	1	19	804.5	52.0	780–829
	2	15	767.8	60.8	740–795
	3	4	825.7	36.7	772–879
2	3	8	983.4	92.4	945–1021
3	1	8	739.6	14.8	702–777
	2	4	733.5	9.0	680–786

Entries are mean value ± standard deviation in Newtons.

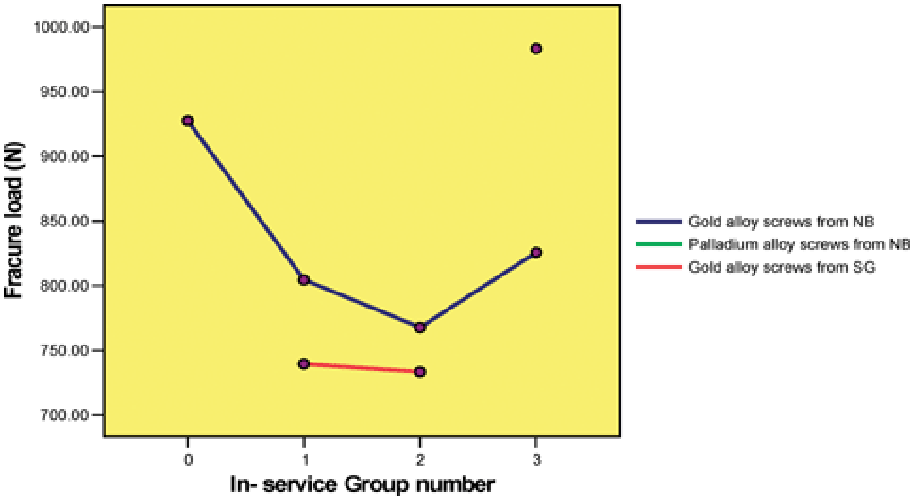

Figure 7

Mean fracture load values for the three prosthetic screw groups with different alloy compositions. Additionally, the effect of in - service time on mean fracture load values is shown for each group.

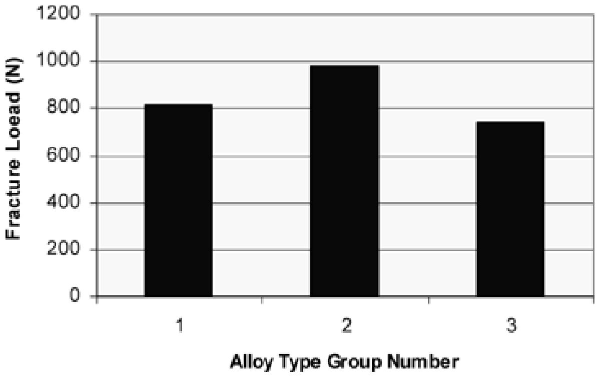

Figure 8

Mean fracture load values for the three screw groups classified by alloy type (composition). (Significant difference between fracture values for the three groups at p < 0.001) 1 = Gold alloy screw from NB, 2 = Palladium alloy from NB, 3 = Gold alloy from SG.

Table 10. Tukey multiple range test II (*p* < 0.001)

Group number based on alloy composition (see Table 2)	**Mean fracture load value (N)**
1	815.8[a]
2	983.4[a]
3	737.61[b]

Statistically significant difference exists between values with different superscript letters.

Retrospective scanning electron microscopy examinations of the fracture surfaces (at shank areas) of arbitrarily selected retaining screws for each alloy type revealed equiaxed dimple formation in all screws indicative of ductile fracture (Fig 9); however, the dimples formed on fracture surfaces of palladium alloy screws were extremely fine dimples compared to those formed on fracture surfaces of gold alloy screws. This may be due to formation of fine coalescence voids around the dispersed secondary precipitate within the palladium alloy matrix previously mentioned and discussed in Part 2 of this series.

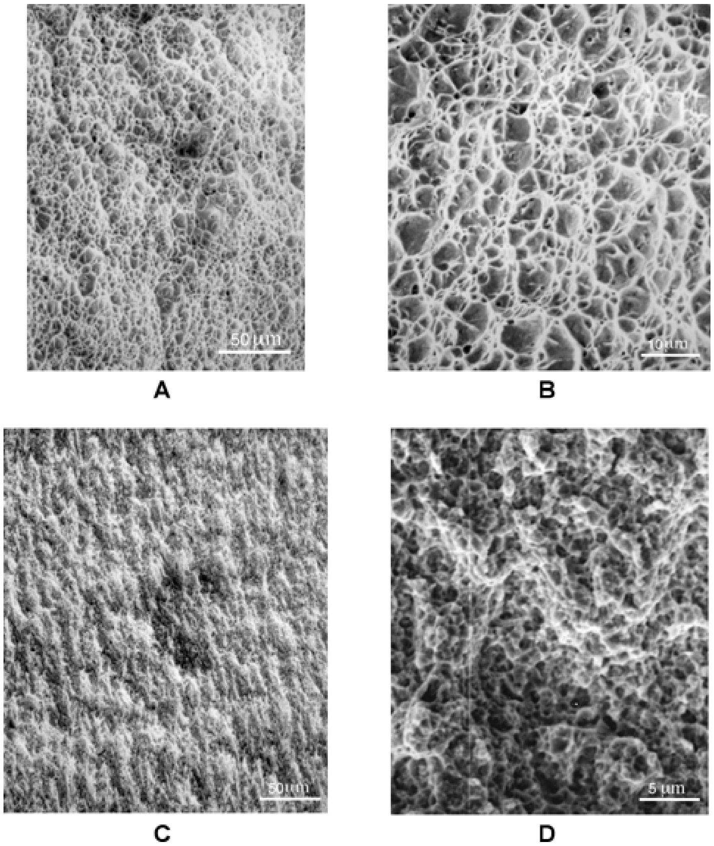

Figure 9

SEM fractographs of prosthetic retaining screws from NB. (A) and (B): Gold alloy screw. (C) and (D): Palladium alloy screw. Magnification is at ×300 for (A) and (C), whereas (B) is ×1500, and (D) is ×3000. Fracture in both alloys occurred by dimple rupture. Fine dimples in (C) and (D) indicate microvoids coalescence in the fracture mode.

Discussion

Preload is tension in a screw created when a torquing force is applied to the screw head. Normally, when a screw is tightened most of the screw responds elastically (plastic deformation occurs only at spots of machining microroughness and asperities at thread flanks). Thus, preload produces a clamping force between the screw head and its seat. The behavior and life of a screw joint depends mainly on the magnitude and stability of that clamping force.[10, 11] In general, the greater the clamped force (preload), the tighter the clamped joint; however, preload values should not be too high and should be within the elastic limit, otherwise retaining screws may yield or break under repeated functional bite forces. On the other hand, the preload values should not be too low; otherwise the retaining screws loosen under repeated functional forces.

Clinical studies evaluating the adequacy of fixed detachable hybrid prostheses show that screw loosening is a common complication after insertion of the prosthesis, and screw fracture can follow as a result of loosening of the screw joint leading to catastrophic failure of the prosthesis.[12, 13] Since several variables are involved, the nature of retaining screw loosening is complex. These variables may include thermal changes, magnitude of occlusal forces, cantilever length, occlusal scheme, chewing patterns, and short/long-term relaxations. Therefore, prediction of proper preload is somewhat difficult.

Short-term relaxation, sometimes called embedment relaxation or settling of prosthetic retaining screws, is the initial preload loss (about 10%) after the first tightening of the screw.[5, 10] It occurs as a result of permanent flattening of machining microroughness. It has been found that 2% of the initial preload value reduction occurred within 5 minutes of torque application as a result of initial and short-term relaxation phenomenon.[7] Additionally, there was an 8% increase in mean preload values from the first to the fifth repeated torque, and a 16% increase from the first to the tenth repeated torque.[7] The gradual increase in preload was related to the gradual elimination of microroughness on the thread mating surfaces allowing larger and smoother contacts. Due to this settling effect, it has been suggested that the use of prosthetic retaining screws from the try-in appointment might help obtain optimal preload during final torquing at the insertion appointment and that clinicians should remove and retorque prosthetic screws after 1 year in service.[7]

In the present study, however, short-term relaxation phenomena were not examined during torque preload testing, because it was presumed that the phenomenon does not exist in retrieved and used screws.7 Additionally, the preload values were found to be inconsistent with previous findings. This study demonstrated a significant reduction in preload values of gold alloy screws from NB compared to similar screws in control groups primarily due to long-term relaxation of prosthetic retaining screws as a result of significant thread deterioration and surface roughening caused by galling and severe deformation of the screw geometry as discussed in Part 1 of this series. Accordingly, the coefficient of friction increased after long periods of in-service time leading to a reduction of the preload values. Therefore, clinicians should expect that an increase of in-service time would decrease the preload values of retaining screws unless galling is delayed and/or prevented. An increase in the preload values may be expected initially when the machining microroughness is eliminated after first torquing or during initial wear.[14] If the wear reaches the galling stage, it will increase surface roughness, thus reducing preload values. This is consistent with previous findings where investigators have reported a reduction in preload values after repeated tightening and loosening cycles of titanium alloy abutment screws.[15]

In the present study, although the retaining screws from SG were considered to be compatible with the components of the original NB system, they had a significant difference in preload values at 10 Ncm torque (Table 5). The significant difference in preload values was attributed to the geometrical design and material property variations. This result is consistent with previous findings where it was reported that screws from different manufacturers, even though they looked alike, withstood different maximum preload torque before fracture.[4] It was suggested that interchanging implant retaining screws could introduce new and unknown variables that would affect long-term survival of implant fixtures and/or the implant prosthesis.

Retrievability of the prosthetic retaining screw is considered the main advantage of its use in fixed detachable hybrid prostheses. Therefore, it has been suggested that the screw must remain secure under varied loads, and any early failure caused by a decreased tensile strength would negate the retrievability advantage.[7] The observation of long-term relaxation and wear in Part 1 of this series suggests that total stability of retaining screws under varied in-service loads for long periods of time without retightening may not be attainable. There is a lack of data regarding in-service behavior of prosthetic retaining screws, and it is difficult to predict the fatigue life of these materials. Previously, only in vitro studies evaluated the effect of increased torque forces and repeated torque on the ultimate tensile strength of prosthetic retaining screws.[4, 8]

In the present study, a significant difference was found between the fracture load values of palladium alloy screws from NB, gold alloy screws from NB, and gold alloy screws from SG. Palladium alloy screws had the highest fracture load values, whereas gold alloy screws from NB and SG had the lowest (Fig 8). This may be attributed to the hardness, major alloy constituents, and microstructural differences. This finding is supported by previous studies that indicated a significant difference in the fracture load values of prosthetic retaining screws obtained from two manufacturers (3i and NB).[9, 16] Additionally, the present findings reinforce previous conclusions that "components made by different manufacturers may look alike but not behave alike."[9]

An unexpected finding of the present study was that gold alloy screws from NB and SG showed a gradual reduction of the fracture load values with increasing time in service (Fig 7). This finding raises the question of whether an increase of in-service time will decrease the tensile strength of retaining screws. From this study alone, it is difficult to determine the actual cause of the reduction in fracture load values; however, there are two possible reasons for this phenomenon. The first is that because the tested screws (including controls) covered a 5-year period, the manufacturing process may have changed over that period of time. The significant microstructural and thread-manufacturing process differences of gold alloy screws from NB support this possibility. This possibility is also supported by previous findings of significant differences in the fracture load values of 3i and NB prosthetic screws from two lots.[9, 16] These studies should raise the concern of clinicians regarding the differences in fracture load values between different lots made by the same manufacturer. The second reason is that reduction of fracture load values may be a result of adhesive wear, which might have led to a significant reduction in cross-sectional area of the screws. As mentioned in Part 1 of this series, wear observed in this study was associated with galling and pulling away of surface material. Whenever wear reaches this stage, it will cause alteration of dimensions over a period of time.[17] Small screws, such as retaining screws, are very sensitive to small changes in dimension. Additionally, retrospective analysis of the fracture sites of selected screws showed that the greater the diameter of the fracture surface, the higher the fracture load value.

Regardless of the actual cause of fracture load value reduction in this study, our findings reinforce previously raised dilemmas where the mean ultimate tensile strength varied from lot to lot for screws of the same manufacturers, and where 10 Ncm preload torque (manufacturer's recommendation) corresponds to a screw tension just below the yield strength, a clinical conundrum for optimum preload.[16] The increase of in-service time of retaining screws resulted in a decrease in fracture load values. It is true that higher preload provides higher clamping force and prevents screws from self-loosening when they are exposed to shock/vibration or thermal cycles; however, higher preload increases tension in the screws, making them more susceptible to stress and cracking.[10, 11] Therefore, at higher preload for screws with compromised tensile strength, the more inevitable stress cracking and/or catastrophic failure will be.

Lastly, misuse and improper assembly can be considered one of the causes of material failures or shortening of in-service life. Early failure of prosthetic retaining screws might occur if they are placed under conditions for which they are not designed. In this study, two conical gold alloy-retaining screws from NB ($18B_1$ and $5A_2$) were retrieved from fixed detachable hybrid prostheses, while the gold cylinders used were designed for a flat-headed retaining screw. The head of the conical screw is very wide for gold cylinders designed for flat-headed screws. Therefore, if they are used or assembled together, there will be a significant adverse effect on the torque/preload relationship. Most of the torque will be used to push the wide conical head through a narrow gold cylinder hole, thus minimizing thread engagement and final preload values. For this reason, preload values obtained for both conical screws were extremely low (34 N). It was not possible to detect any fatigue cracks on the two conical screws; however, there was severe metal wear and plastic deformation/damage on the threads. This means that the implant fixtures located where the conical retaining screws were used to attach the hybrid prosthesis were almost useless since the clamping force (preload) was 34 N (a negligible value).

In this study, tensile fracture load values of prosthetic retaining screws decreased with increased in-service time; however, from this study alone, it is not possible to determine whether this relationship is causal. A more highly controlled study needs to be performed using prosthetic retaining screws from the same manufacturer and lot number in several patients treated with fixed detachable hybrid prostheses. The screws should be retrieved after various periods of time and tensile fracture load values measured. Future studies should also focus on mating threads' optimal coefficient of friction and shear strength, which are important factors in maintaining preload and resisting galling.

Clinical significance

Consideration of the initial question raised in this study relates to whether preload and fracture load values decrease as prosthesis in-service time increases. This study demonstrates that the preload value decreases as the in-service time increases. Based on this study, retaining screws with as low as 160 N preload values served for 10 years, and retaining screws with 260 N values showed failure after 2 years. Therefore, it is more important to maintain the original intended preload values rather than trying to achieve some optimal preload value. Following the previously suggested maintenance protocol in Part 1 of this series may not only minimize/delay galling (surface roughening), but may also maintain the original intended preload each time retaining screws are retorqued. One of the goals of clinicians should be to reduce surface roughening caused by galling.

Conclusions

The results of this study suggest that:

1) Galling (surface roughening) and/or geometrical design deformation may decrease the intended preload values with increased in - service time in fixed detachable hybrid prostheses.

2) The reduction of the fracture load value may be related to the increase of in - service time. From this study alone, it is impossible to determine the actual cause of the reduction of fracture load values for the examined retaining screws.

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