Evaluation of the Precision of Fit Between the Procera Custom Abutment and Various Implant Systems

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Purpose: *It has been suggested that the CAD/CAM Procera custom abutment may be universally applied with multiple implant systems. An acceptable fit between the internal hexagon of an abutment and the external hexagon of various implant systems, along with true interchangeability of the Procera abutment screw, would support this concept. This study determined the precision of fit of the CAD/CAM-produced Procera abutment onto the external hexagon and bearing surfaces of implants from 6 implant manufacturers and the interchangeability of the Procera abutment screw with these systems.* ***Materials and Methods:*** *This investigation consisted of 3 parts: (1) direct measurement of the internal hexagon and bearing surface of each Procera abutment and the external hexagon and the bearing surface of 6 implants from 6 different systems, (2) radiographic examination of 30 Procera abutment-implant junctions following tightening to 32 Ncm to determine the precision of fit between the bearing surfaces and the top of the external hexagon of the implant with the superior surface of the internal hexagon of the abutment, and (3) examination of 3 abutment screws and 3 implants from the various manufacturers for interchangeability based on American National Standards.* ***Results:*** *The mean flat-to-flat external hexagons of the implants measured between 2.67 and 2.69 mm. The Procera abutment's flat-to-flat internal hexagon measured 2.73 mm. The height of the various implant systems' external hexagon ranged from 0.69 to 0.81 mm. The height of the Procera abutment blanks was 0.90 mm. Radiographic examination demonstrated that not all of the manufacturers' screws fit appropriately within the internal screw bore of the Procera abutment. The internal bore of all implant systems studied had a metric thread designation of M2 × 0.4 − 6H. The metric thread designation of all abutment screws examined was M2 × 0.4 − 6g. The greatest variations in the dimensions of the abutment screws measured were seen in the diameter of the screw head, which ranged from 2.12 to 2.69 mm.* ***Discussion:*** *The Procera abutment's internal hexagon fit the external hexagon of all implant systems evaluated. The Procera abutment screw fit the internal screw bore of the implant systems tested.* ***Conclusion:*** *The Procera abutment with its screw can be universally applied to the implant systems studied. This fact, plus the CAD/CAM feature of this system, would thus provide a dynamic approach to satisfying the design and spatial needs of implant placements observed clinically.* INT J ORAL MAXILLOFAC IMPLANTS 2003;18:652–658

Key words: *CAD/CAM, dental abutments, dental implants, dental prosthesis retention*

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The ultimate success of any implant-supported prosthesis is directly related to the precision of fit between the components that form the implant pillar.[1–7] The precision of fit begins at the junction of the implant and the abutment placed onto the implant. The bearing surface of the implant and the opposing bearing surface of the implant abutment form a screw joint that must maintain an established preload throughout the life of the implant restoration. Maintenance of joint stability is considered a function of the preload stress achieved in the screw when the suggested tightening torque is applied to clamp the abutment to the implant. Joint stability is influenced by the geometry of the screw, the contact between the screw and its bore, contact between the bearing surfaces, friction between the various implant parts, and the material properties of the screws.[8–12] Fit tolerance between the external hexagon of the implant and the internal hexagon of the abutment has been suggested as another factor influencing the stability of the abutment/implant screw joint.[6,7] Binon and McHugh[13] and Binon[14,15] suggested that the fit between these 2 hexagons in this joint assembly should permit less than 5 degrees of rotational movement to sustain a stable screw joint.

In a recent study, 4 Brånemark System abutment designs (Nobel Biocare, Göteborg, Sweden) were examined for fit between the abutment internal hexagon and the implant external hexagon.[16] The CeraOne (SDCA 068), EsthetiCone (SDCA 136), Procera custom abutment, and AurAdapt (DCA 1086-0) all demonstrated a maximum amount of rotation of the abutment around the implant hexagon of less than 3.5 degrees, thereby satisfying the tolerance requirement suggested by Binon and McHugh. The Procera custom abutment demonstrated an additional advantage of the CAD/CAM technology used in its fabrication. (Few if any clinical situations cannot be resolved with the software developed for the design and fabrication of this abutment.) This design advantage would offer a universal application as an abutment for external-hexagon implant systems, if an acceptable fit could be demonstrated to exist between the internal hexagon of the abutment and the external hexagon of other implant systems. Therefore, a study was designed to assess *(1)* the precision of fit of the CAD/CAM-produced Procera abutment onto the external hexagon and bearing surfaces of implants from various implant manufacturers, and *(2)* the interchangeability of the Procera abutment screw with these systems. The specific aim of this investigation was to determine the universal application of the Procera custom abutment for the most commonly used external-hexagon implant systems. The null hypothesis of this study was that there was no difference in the precision of fit of the CAD/CAM abutment internal hexagon and the 5 external-hexagon implant systems chosen for this investigation.

MATERIALS AND METHODS

The following implants were evaluated for precision of fit of their external hexagons with the internal-hexagon bearing surface of the Procera custom abutment. The implant components were ordered from each manufacturer. All implants and abutment screws from a specific manufacturer were from the same lot number, respectively.

1. Brånemark System, Conical Self-Tapping 3.75×10-mm implants (Nobel Biocare)
2. Lifecore Restore 3.75×10-mm implants (Lifecore Biomedical, Chaska, MN)
3. Implant Innovations (3i) System 3.75×10-mm implants (West Palm Beach, FL)
4. ImplaMed 3.75×10-mm implants (Sterngold-ImplaMed, Attleboro, MA)
5. Paragon Taper-Lock 4.0×10-mm implants (Encino, CA)

This investigation consisted of 3 parts. Part 1 of this study involved the direct measurement of the external hexagon and the bearing surface of each implant and the internal hexagon and bearing surface of each Procera abutment. The 3-dimensional lateral walls of each hexagon were measured using a Mitutoyo Digimatic Caliper (Kawasaki, Japan) with an accuracy of ± 1.0 µm. The mean data derived in this manner was then used to determine whether the Procera abutment would fit onto the implant hexagon of each implant system investigated.

In part 2 of this study, the abutment-implant junction was examined radiographically to determine the precision of fit between *(1)* the bearing surfaces and *(2)* the top of the external hexagon of the implant with the superior surface of the internal hexagon of the abutment. Thirty Procera abutments were produced by CAD/CAM with a uniform collar and height. Using the CAD/CAM fabrication process, a vertical line was milled at the manufacturing facility on the outer surface of the abutment. The line was milled at a location opposite one of the flat surfaces of the internal hexagon, as a reference to uniformly and reproducibly orient each sample used in the radiographic portion of the study. Each implant and its Procera abutment formed one sample. Each sample was placed in a rigid device to ensure solid fixation without rotation for tightening of the abutment screw (Fig 1). The Procera custom abutment was tightened using the abutment screw specific to each of the 5 different implant systems. Each abutment screw was tightened to 32 Ncm using a calibrated electronic torque controller and the internal countertorque device (Nobel Biocare).

Following tightening, the reference marker on the outer surface of the abutment was oriented perpendicular to the axis of the radiographic source (Fig 2). The radiographic images were recorded on conventional film using an exposure of 0.4 seconds and a voltage of 70 kVp. After the radiograph was made, the sample was rotated 90 degrees, and the radiographic procedure was repeated.

Visual inspections of the abutment screws of the various implant systems demonstrated dimensional

Fig 1 Tightening of abutment screw to 32 Ncm after implant/Procera abutment sample is placed in a holding device to ensure solid fixation.

Fig 2 Positioning of the abutment-implant complex for radiographic assessment. Photograph demonstrates the angle of the radiographic source. The camera lens is positioned as if it were the head of the radiographic tube. The reference marker *(black)* located opposite one of the flat surfaces of the internal hexagons on the outer aspect of the Procera abutment was oriented perpendicular to the axis of the radiographic source.

and design differences. The screw head configuration could potentially limit proper seating of the screw head onto the clamping ledge in the Procera abutment bore. If this was the case, then the Procera abutment might not be an acceptable abutment for these external-hexagon implant systems. However, if the abutment screw designed for the Procera system was interchangeable with the specific screws for each of the implant systems, then the Procera abutment with its screw would be an acceptable abutment for the implant systems studied. Therefore, part 3 of this study was initiated to determine the interchangeability of the Procera abutment screw with the 5 abutment screws of the dental implant systems evaluated.

All screw threads have a standard form of profile or geometry and are usually made according to the International Organization for Standardization (ISO). Two widely used standards are the American National (Unified) thread and the metric threads. The basic profile of metric screw thread is specified in ISO 68 and on ANSI/ASME B1.13M-1983 (R1989) American National Standard.[17]

Three abutment screws and 3 implants from the Procera, Brånemark, Lifecore Restore, ImplaMed, 3i, and Paragon systems were examined for interchangeability based on ANSI/ASME B1.13M-1983 (R1989) American National Standard.[17] This standard assesses the major determinants of interchangeability by the screw profile (ANSI/ASME B1.21M), ie, the pitch and tolerance. The standard includes general metric criterion for a 60-degree symmetric screw thread with a basic ISO 68–designated profile (Fig 3). The basic thread profile is the

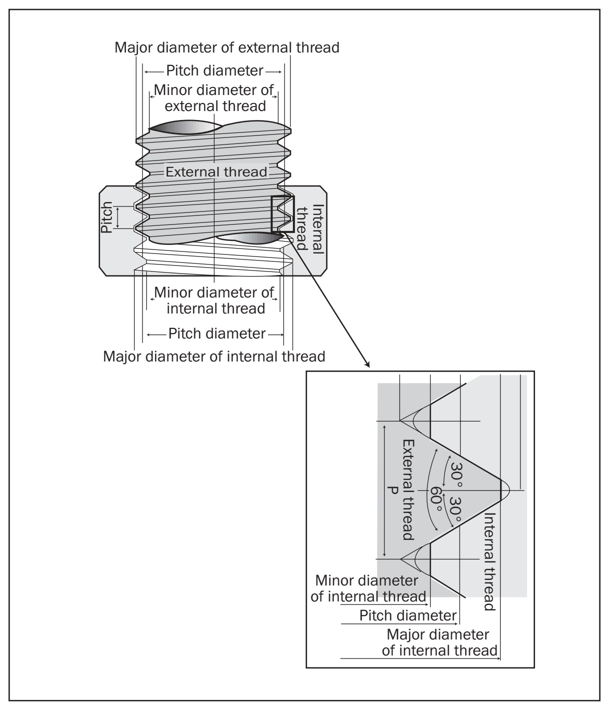

Fig 3 Diagram of a basic thread profile, internal and external thread diameters, and pitches identified. The M profile is the cyclical outline in an axial plane of the boundary between the external and internal threads with a 60-degree symmetric thread angle and a thread form in which the crest form of the major external thread is flat, permitting corner rounding. This profile is used where high fatigue strength is required, as is the case with an implant abutment screw.

cyclical outline in an axial plane of the boundary between the external and internal threads. The ISO 68 basic profile for metric screw threads is the basic

M profile, with 60-degree symmetric threads. Figure 3 shows the thread geometry of the metric M profiles. The basic M profile indicates that the thread angle is 60 degrees and a thread form in which the crest form of the major external thread is flat, permitting corner rounding.[18] This profile is used where high fatigue strength is required, as is the case with an implant abutment screw. These are expressed by the metric M value.

Tolerance is defined by a series of numeric grades. Each grade provides numeric values for the various nominal sizes that correspond to the standard tolerance for that grade. The system provides a series of tolerance grades for each of the 4 screw thread parameters: diameter of the internal thread, diameter of the external thread, internal thread pitch diameter, and external thread pitch diameter (Fig 3). The tolerance position is the deviation from the position of the pitch diameter and is indicated by a letter. A capital letter is used to indicate internal threads and a lowercase letter is used to indicate external threads. This system provides for a series of tolerance positions for internal and external threads.

The combination of a tolerance position with a tolerance grade signifies the tolerance class. It specifies the fundamental deviation and the tolerance for the pitch and the external and internal thread diameters. A designation of tolerance is given first for the grade, then the tolerance position. If the 2 grades and positions are identical, it is not necessary to repeat the symbols. Thus, 6g alone stands for 6g6g and 6H alone corresponds to 6H6H.[18]

The tolerance grades for Standard ANSI/ASME B1.13M were selected from those given in ISO 965/1 tolerance practices.[18,19] The ISO 965/1 tolerance practices are based on a system of limits and fits. The limits of the tolerances (the amount of variation) on the mating parts, together with the deviation from the basic size (allowance), determine the relative precision fit of the thread assembly.

Metric screw threads are identified by the letter (M) for the thread profile, followed by the nominal diameter and the pitch (expressed in millimeters), separated by the sign (×) and followed by the tolerance class, which is separated by a dash (–) from the pitch. To determine the metric screw thread designation, the screw and implants were measured using a series of go and no-go gauges. These gauges are industry standards used to verify the screw and screw bore dimensions (Figs 4a and 5a). To determine the thread designation of the implant bore a series of go/no-go gauges were screwed into the implant bore until the correctly fitting gauge was identified (Figs 4a and 4b). In a like manner, the abutment screw was screwed into a series of go/no-go gauges until the properly fitting gauge was identified (Figs 5a and 5b).

In addition to the screw thread designation, a Mitutoyo Digmatic Caliper was used to measure the diameter of the screw head, the diameter of the shank of the screw, and the diameter of the threaded portion of the screw.

RESULTS

Part 1: Direct Measurement

The 3 measurements for each of the three flat-to-flat and height distances for each implant hexagon are recorded in Table 1. The mean flat-to-flat hexagon dimensions of the implants ranged from 2.67 to 2.69 mm. The Procera abutment's flat-to-flat dimension was 2.73 mm. The height dimension of the implant systems' external hexagon ranged from 0.69 to 0.81 mm. The height of the Procera abutment blanks was 0.90 mm. From the measurement data, it appears that the Procera abutment would fit onto all of the implants measured in this study.

Part 2: Radiographic Assessment

During the abutment connection procedure, it was noted by the investigator that the Procera-Paragon assembly did not appear tight, although the torque driver had reached the 32-Ncm tightening torque. Therefore, radiographic assessment was not done for the Paragon samples. The initial visual evaluation of the fit between the implant and abutments appeared acceptable for the remaining systems. However, radiographic examination of the Lifecore Restore and 3i samples demonstrated that the manufacturers' screws did not fit appropriately within the internal screw bore of the Procera abutment (Figs 6 and 7). It appeared that the dimensions and design differences of the screw heads from these implant systems would not permit proper seating of the screw head onto the clamping ledge of the Procera abutment bore (Figs 6 and 7).

Part 3: Abutment Screw Interchangeability

Table 2 categorizes the internal bore of the various implants and the dimensions of threads of the abutment screws. The internal bore of all implant systems studied had a metric thread designation of M2 × 0.4 – 6H. The metric thread designation of all abutment screws examined was M2 × 0.4 – 6g. The diameters of the screw heads, the diameters of the shanks of the screws, and the diameters of the threads of the screws are listed in Table 3. The greatest variations in the dimensions of the abutment screws measured were seen in the diameter of

Fig 4a The go/no-go gauge that was used to determine the thread designation of the implant bore.

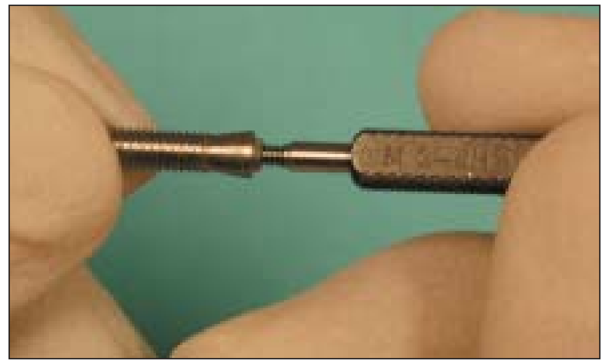

Fig 4b *(Right)* The go/no-go gauge is placed inside implant bore.

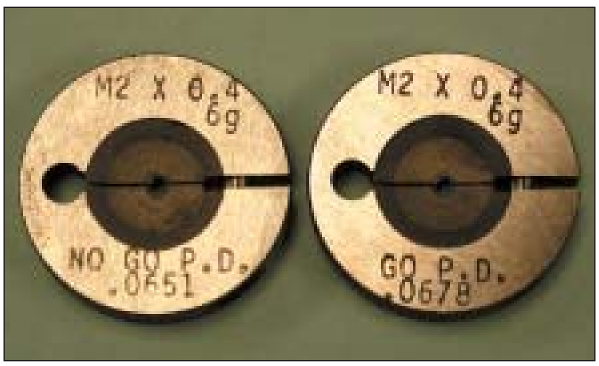

Fig 5a The go/no-go gauge that was used to determine the thread designation of the abutment screw.

Fig 5b The abutment screw is placed inside the go/no-go gauge.

the screw head. The diameter of the screw head of the Procera abutment screw was 2.52 mm. The diameters of the screw head of the abutment screws for ImplaMed (2.59 mm) and 3i (2.69 mm) were larger than that of the Procera abutment screw head, while the diameters of the Lifecore Restore (2.43 mm) and the Paragon (2.15 mm) abutment screws heads were smaller. The Paragon UCLA-type abutment screw head diameter showed the largest variation from the Procera screw; it was 0.37 mm smaller than the diameter of the Procera abutment screw.

Table 1 The Mean Flat-to-Flat Width and Height for the Procera Abutment and Each Implant Hexagon

Implant system	Width ± SD (mm)	Height ± SD (mm)
Procera	2.73 ± 0.02	0.9
Brånemark	2.69 ± 0.02	0.70 ± 0.01
Lifecore	2.67 ± 0.01	0.81 ± 0.02
ImplaMed	2.69 ± 0.01	0.69 ± 0.02
3i	2.69 + 0.01	0.70 ± 0.02
Paragon	2.69 ± 0.01	0.79 + 0.01

DISCUSSION

From the measurement data (Table 1), it would appear that the Procera abutment's internal hexagon should easily accept the external hexagon of each of the implant systems evaluated when the abutment is placed onto the implant hexagon. Visual inspection of each sample demonstrated a clinically acceptable junction between the abutment and the implant. However, examination of the radiographic specimens (Figs 6 and 7) demonstrated that the Lifecore Restore and 3i screws did not fit appropriately within the internal screw bore or onto the bore ledge of the Procera abutment. The Lifecore screw is tapered at the junction between the screw head and the shank of the screw, and this tapered portion of the abutment screw appeared to wedge itself with the bore opening beneath the screw bore ledge. Radiographically, the bore ledge appears to be deformed by the tapered part of the Lifecore abutment screw, in contrast to the Procera abutment screw (Figs 7 and 8).

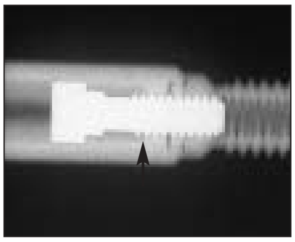

Fig 6 Radiograph of the Procera abutment, 3i abutment screw, and 3i implant. The arrow indicates the base of the clamping ledge of the Procera abutment bore. Note its distance from the head of the abutment screw.

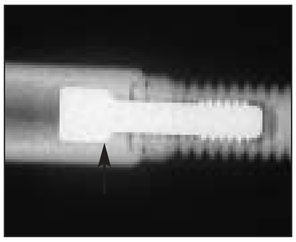

Fig 7 Radiograph of the Procera abutment, Lifecore Restore abutment screw, and Lifecore Restore implant. The arrow indicates the interface between the head of the abutment screw and the clamping ledge of the Procera abutment bore.

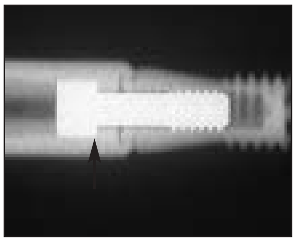

Fig 8 Radiograph of the Procera abutment, Procera abutment screw, and Brånemark System implant. The arrow indicates the interface between the head of the abutment screw and the clamping ledge of the Procera abutment bore.

Table 2 The Metric Thread Design of the Internal Bore of the Various Implants and the Dimensions of Threads of the Abutment Screws

Implant system	Implant internal bore	Metric screw external thread
Procera	—	M2 × 0.4 – 6g
Brånemark	M2 × 0.4 – 6H	M2 × 0.4 – 6g
Lifecore	M2 × 0.4 – 6H	M2 × 0.4 – 6g
ImplaMed	M2 × 0.4 – 6H	M2 × 0.4 – 6g
3i	M2 × 0.4 – 6H	M2 × 0.4 – 6g
Paragon	M2 × 0.4 – 6H	M2 × 0.4 – 6g

Table 3 Mean Measurements of the Diameter of the Screw Head, the Diameter of the Shank of the Screw, and the Diameter of the Thread of the Screw in mm (n = 3)

Implant system	Screw head diameter	Shank diameter	Thread diameter
Procera	2.52	1.46	1.93
Lifecore	2.43	1.44	1.92
ImplaMed	2.59	1.93	1.93
3i	2.69	1.52	1.94
Paragon	2.12	1.48	1.93

The mean measurements of the diameter of the screw heads (Table 3) further support the radiographic findings. The diameter of the Procera abutment screw head (2.52 mm) was smaller than the diameter of the 3i (2.69 mm) and ImplaMed (2.59 mm) abutment screw heads, while it was larger than the Lifecore Restore (2.43 mm) and the Paragon (2.12 mm) abutment screw heads. This difference in diameter did not allow the 3i abutment screw to seat onto the Procera abutment screw ledge in the Procera screw bore. Figure 6 demonstrates that because of the screw head diameter, the Procera abutment bore did not accommodate the 3i screw head. The screw did not seat against the internal abutment screw bore. After tightening the screw to 32 Ncm, a loose screw joint was noted.

A logical explanation for the loose Procera/Paragon connection made during abutment screw tightening may be found in the mean measurement of the Paragon screw head. The diameter of the Paragon UCLA-type abutment screw head was 0.40 mm smaller than the diameter of the Procera abutment screw. This difference in diameter may have resulted in an inability of the screw head to clamp the internal bore ledge of the Procera abutment, resulting in a loose connection.

During part 3 of the study, the screw threads and the threads of the internal bores of the implant systems studied were measured using the M profile go/no-go gauges. The threads of all abutment screws were measured as M2 × 0.4 – 6g. The implant internal screw bores for all implant systems studied also measured the same, at M2 × 0.4 – 6H. This led the investigators to conclude that the Procera abutment screw, which was designed to fit the Procera abutment internal bore, would also fit into the internal threading of all of the external-hexagon implants studied. The data supporting this conclusion clearly demonstrated that the Procera abutment with the Procera gold abutment screw would permit its universal application with the implant systems studied. Since the measurement data regarding the Procera gold abutment screw indicated a thread designation of M2 × 0.4 – 6g, which should fit into the thread designation M2 × 0.4 – 6H of all the implant systems evaluated, the Procera abutment screw was used to assemble the Procera abutment onto all implant systems studied.

Visual observations of the abutment-implant joint and the tightness of the abutment onto the implant were found to be subjectively acceptable. This fact, along with the CAD/CAM design features of the Procera abutment system, would thus provide an alternative approach to satisfying the design and spatial needs that are often unique and troublesome with implant placements observed clinically. The advantages of the Procera abutment are a noteworthy addition to technologically advanced design and fabrication of customized implant abutments.

CONCLUSION

Based on the data collected in this study, the following conclusions can be made:

1. The Procera custom abutment internal hexagon fit the external hexagon of all implant systems evaluated.
2. The 3i, Lifecore Restore, and Paragon UCLA-type abutment screws did not fit the Procera abutment screw bore.
3. The Procera abutment screw fit the internal screw bore of the implant systems tested.
4, The Procera abutment could be considered for universal application with the implant systems studied.

ACKNOWLEDGMENTS

This work was supported by Nobel Biocare/University of Michigan "Center for Excellence" and Lifecore Biomedical.

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