

BIOMECHANICAL AND HISTOMORPHOMETRIC ANALYSES OF MONOCORTICAL SCREWS AT PLACEMENT AND 6 WEEKS POSTINSERTION

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Maxillofacial screws are increasingly being used in orthodontics to provide anchorage for tooth movement. The objective of this study was to determine the biomechanical stability as well as the bone tissue response of screws at 6 weeks postinsertion in a canine model. Seven skeletally mature male dogs received 102 screws (2 × 6 mm or 2 × 8 mm) at predetermined sites. Twenty screws became loose or were lost during the 6-week undisturbed healing period. Forty-eight screws were randomized for mechanical testing and 34 for histology. Peak pullout strength was recorded and ~80- μ m sections were examined for histomorphometric parameters. Statistical analyses were conducted by analysis of variance and Tukey-Kramer method. Mean \pm SE peak pullout strengths for the various sites ranged from 153.5 \pm 37.6 N to 389.3 \pm 32.5 N with no significant ($P < .05$) differences at immediate placement and 6 weeks postinsertion. Bone contact ranged from 79% to 95%. Histomorphometric analyses indicated higher bone formation rate in the mandible than in the maxilla and a gradient of decreasing turnover with increasing distance from the screw interface. These results provide the clinical orthodontist with an estimate of the holding power of these screws and an understanding of early biological healing response associated with self-drilling screws.

INTRODUCTION

Establishing anchorage for orthodontic movement is critical to treat malocclusions successfully. Skeletal anchorage involves using screws or implants inserted into bone to support orthodontic tooth movement. Recent case reports¹⁻¹⁰ have drawn much attention to this promising form of anchorage. Although multiple case re-

ports advocate the use of screws for orthodontic anchorage, specific questions remain regarding their clinical use. Reported success rates of screws vary from 50% to 89%,¹¹⁻¹³ with success defined as sustenance over the course of orthodontic treatment and the absence of inflammation and clinical mobility. Reported healing time before load application varies in the literature, with some reports of immediate loading^{5-7,14,15} and others allowing 2

weeks of soft tissue healing before loading of these screws.^{2,16,17}

The objective of the current study was to evaluate the holding power of monocortical screws as a function of cortical bone purchase and to examine their adaptation physiology to bone at 6 weeks postinsertion (T_6). The time point of 6 weeks was chosen because it allowed for the initial osseous healing and reflected a common clinical practice for many orthodontists. It was hypothesized that (1) peak pullout strengths and cortical bone thickness at the sites of screw insertion would be different at T_6 when compared with immediate placement (T_0) and (2) adaptation physiology of these screws would consist of modeling and remodeling events similar to those observed in bone supporting endosseous implants.

MATERIALS AND METHODS

Seven healthy skeletally mature male beagle dogs received a total of 102 self-drilling screws (Synthes USA, Monument, Colo). The animal protocol was approved through The Ohio State University Institutional Laboratory Animal Care and Use Committee. All screws were 2 mm in diameter and were manufactured from a titanium alloy (Ti-6Al-7Nb). The dogs were 14 to 18 months old and weighed 9 to 14 kg. Screw insertion sites were randomly assigned to either mechanical pullout testing or histological analyses before start of study. Assignments were made to ensure even but random distribution of sites for each test. Approximately two thirds of the screws were used for the mechanical testing and one third were used for the histological analyses.

At the time of surgery, each dog was sedated with acepromazine (2 mg), anesthetized with intravenous (IV) ketamine (100 mg) and diazepam (5 mg), intubated, and maintained on isoflurane (2.0%–2.5%). Lidocaine HCl 2% with 1:50 000 epinephrine (0.5 mL) was infiltrated at each surgical site for hemostasis. Each dog had 14 to 15 screws placed in predetermined sites in the maxilla and mandible. The methods have been described in detail.¹⁸ Depending upon the availability of the alveolar bone stock for screw placement, the site of insertion of the screw was covered by either attached or movable mucosa. In sites covered by attached mucosa, each screw was inserted directly into the cortical bone until the undersurface of the screw head was approximately flush with the attached tissue. In sites covered with movable mucosa, an incision of approximately 2 to 3 mm was made through the mucosa to the bone. Soft tissue was reflected with a periosteal elevator, and the screw was inserted until the undersurface of the head had approximately 0.5 mm of clearance with the bone surface. No pilot hole was drilled before insertion of the screws. The screws were inserted perpendicular to the cortical bone surface with the intent of obtaining monocortical anchorage. In all cases, care was taken to avoid trapping soft tissue in the screw threads or compressing soft tissue under the screw heads. One operator inserted all screws with a hand driver. In the palate, 8-mm-length screws were used to accommodate the increased soft tissue thickness; 6-mm-length screws were used in the remaining sites.

All dogs received buprenorphine (0.12 mg) before recovery from anesthesia. Oral amoxicillin (250 mg) was administered at 12

hours presurgery and then every 12 hours postsurgery for 5 days. Dogs were restricted to a soft diet for 3 days and then fed standard dry dog chow and water. Intravital bone labels were administered IV to mark forming bone surfaces, with tetracycline (10 mg/kg) administered 8 days and 1 day before screw placement and calcein (5 mg/kg) administered 33 days and 40 days after screw placement. The screws were allowed to heal undisturbed for 6 weeks.

After the healing period, each dog was euthanized with pentobarbital IV (6 mL) in accordance with the recommendation of the American Veterinary Medical Association Panel on Euthanasia. Bone specimen preparations for mechanical testing were identical to those reported previously.¹⁸ For histological analyses, ~80- μ m undecalcified sections were obtained by an Exakt system (Exakt Technologies, Oklahoma City, Okla) and following standard protocols.¹⁹ One section was obtained buccolingually through the center of each screw and its supporting bone.

Histomorphometric analyses were performed with an Olympus BX 51 microscope (Tokyo, Japan) with appropriate filters for calcein. All static and dynamic measurements were made at $\times 100$. An intercept and point hit method was used for histomorphometric analyses.²⁰ Bone volume/total volume (BV/TV, %), mineral apposition rate (MAR, μ m/d), and bone formation rate (BFR, %/y) were calculated for the screw-supporting bone (0–4 mm on each side of the implant). Interlabel width to calculate MAR was measured at $\times 200$. For each dog, 2 cross sections of the left femoral middiaphyses were analyzed to provide baseline bone turnover. This is important because variations in cortical bone

TABLE 1

Mean peak pullout strength and cortical bone thickness at 6 weeks postinsertion (T_6) and after immediate¹⁸ placement (T_0)*†

Site	Pullout Strength						Cortical Thickness (mm)					
	T_6			T_0			T_6			T_0		
	n	Mean	SE	n	Mean	SE	n	Mean	SE	n	Mean	SE
Mx Ant	6	153.5 ^A	37.6	8	168.9 ^A	32.5	6	1.25 ^{AB}	0.19	4	1.43 ^A	0.23
Palate	9	204.8 ^A	30.5	11	180.6 ^A	27.3	9	1.59 ^{AB}	0.16	4	1.79 ^{AB}	0.23
Mx Post	8	224.7 ^{AB}	32.7	8	231.1 ^A	32.5	8	1.03 ^A	0.17	5	1.65 ^{AB}	0.21
Mx Mid	8	233.1 ^{AB}	32.6	7	176.9 ^A	34.8	8	1.54 ^{AB}	0.17	6	1.97 ^{AB}	0.20
Md Mid	8	269.7 ^{AB}	32.5	8	275.4 ^A	32.5	8	1.92 ^B	0.17	6	1.98 ^{AB}	0.20
Md Post	8	389.3 ^B	32.5	7	387.5 ^B	34.8	8	1.94 ^B	0.17	4	2.42 ^B	0.23

*Sites with different superscript letters denote significant differences ($P < .05$). No significant differences in peak pullout force and cortical bone thickness were found between T_0 and T_6 at any of the sites.

†Mx indicates maxillary; Ant, anterior; Post, posterior; Mid, midline; Md, mandibular.

turnover ranging from 2% to 10% per year have been reported.²¹ In addition, abnormal femoral values may indicate bone pathology. To analyze the modeling response,²² linear measurements were made of the periosteal, cortical passage, and endosteal thickness from $\times 40$ images of the screw-bone interface by using computer software (AnalySIS, Soft Imaging System GmbH, Munster, Germany). The cortical passage is the thickness of the bone at the time and site of screw placement. These measurements were made on both sides of the screw, and the 2 values were averaged. To measure bone contact with the screw, a line was scribed to identify the external contour of the screw at $\times 100$. Similarly, multiple line segments representing regions of bone contact with the screw were drawn. The ratio of the sum of line segments representing bone contact to the line representing the length of the external contour of the screw was used to calculate the percent bone contact.²³ Between-jaw and among-site comparisons were made for the histomorphometric study because of the clinical relevance of both comparisons.

Statistical analyses

Biomechanical Testing

Pullout force and cortical bone thickness at the sites of screw insertion were each analyzed by a factorial analysis of variance (ANOVA) with animal (with repeated measures), anatomical site, and time point as independent variables. Post hoc testing was done by the Tukey-Kramer method. Peak pullout strength was analyzed with a regression model with cortical bone thickness as the independent variable.

Histomorphometric Analyses

A factorial ANOVA with animal (with repeated measures) and jaw as the independent variables was used to analyze between-jaw differences, and a similar analysis with the Tukey-Kramer method was used for among-site differences. To normalize the distributions, a log transformation was necessary for BFR and MAR data, and a sine transformation was necessary for between-jaw comparisons of BV/TV data.

RESULTS

The 7 dogs survived the experimental period uneventfully.

Twenty of the 102 screws placed in the canine jaws either became loose or were lost during the 6-week period: 12 were in the mandibular anterior site, 4 were in the maxillary anterior site, 2 were in the mandibular posterior site, and 2 were in the palatal site. Of the 82 surviving screws, 48 were tested for peak pullout strength and 34 were processed for histological analyses. On histological examination, 7 of the 34 screws demonstrated fibrous tissue encapsulation and were not analyzed by histomorphometry: 5 were from the maxillary anterior region, 1 was from the maxillary posterior, and 1 was from the mandibular anterior. Results are reported as mean \pm SE.

Biomechanical testing

Pullout Strength

Results of the ANOVA indicated a significant effect for implant site ($F = 11.2$, $df = 5/34$, $P < .0001$). The day (T_0 or T_6) and the site by day interaction were not significant ($P > .50$). The mean peak pullout strengths varied among insertion sites (Table 1) and ranged from 153.5 to 389.3 N. After 6 weeks of healing, mean peak pullout strengths were significantly ($P < .05$) higher in the mandibular posterior site (389.3 ± 32.5 N) than in the maxillary anterior site (153.5 ± 37.6 N) and the palatal site (204.8 ± 30.5 N).

Cortical Bone Thickness

Results of the ANOVA indicated a significant effect for implant site ($F = 7.42$, $df = 5/33$, $P < .0001$). The day and the site by day interaction were not significant ($P > .05$). Cortical bone thickness varied among anatomical sites (Table 1) and ranged from 1.03 to 1.94 mm. Mean cortical bone thickness was significantly ($P < .05$) higher

in the mandibular posterior site (1.94 ± 0.17 mm) and the mandibular midsite (1.92 ± 0.17 mm) than in the maxillary posterior site (1.03 ± 0.17 mm).

A significant ($r = 0.59$, $P < .0001$, $n = 47$) relationship existed between cortical bone thickness and peak pullout strengths at T_6 .

Histomorphometric analyses

The sample size for histomorphometry from each region after excluding for failures was as follows: maxillary anterior, $n = 2$; maxillary mid, $n = 5$; maxillary posterior, $n = 4$; palate, $n = 6$; mandibular anterior, $n = 1$; mandibular mid, $n = 5$; and mandibular posterior sites, $n = 4$. Failures at 6 weeks resulted in a small sample size in the maxillary anterior and mandibular anterior. These 2 sites were not included in the statistical analyses. Results may be seen in Tables 2 and 3, which represent values at T_6 .

Bone Contact

Screw-bone contact of 78% to 94% was evident at T_6 . There were no significant differences between the jaws ($P > .23$) or among the 5 sites ($P > .42$) (Tables 2 and 3).

Bone Volume/Total Volume (%)

There were no significant differences ($P > .47$) between the maxilla and mandible (Table 2). However, when the 5 sites were examined (Table 3), significant ($P < .05$) differences were noted between the palate and the following 3 sites: mandibular posterior, maxillary mid, and maxillary posterior.

Mineral Apposition Rate ($\mu\text{m}/\text{d}$)

There were no significant differences ($P > .25$) noted between the maxilla and mandible (Table 2) or

Site	Variable						
	MAR ($\mu\text{m}/\text{d}$)	BV/TV (%)	BFR (%/y)	PassTh (μm)	PrTh (μm)	EnTh (μm)	BC (μm)
Mandible (n = 9)							
Mean	0.8	85.1	35.5	2017.2	67.8	0.0	94.2
SE	0.2	2.7	9.1	122.6	34.5	0.0	1.0
Maxilla (n = 15)							
Mean	0.7	88.5	11.6*	1571.1	257.0**	24.1	84.7
SE	0.2	1.9	2.0	135.2	54.1	13.0	4.8

†MAR indicates mineral apposition rate; BV/TV, bone volume/total volume; BFR, bone formation rate; PassTh, passage thickness; PrTh, periosteal thickness; EnTh, endosteal thickness; BC, bone contact.

* $P = .002$.

** $P > .03$.

among the 5 sites ($P > .15$) (Table 3). The MAR for the femoral sections was $0.8 \mu\text{m}/\text{d}$.

Bone Formation Rate (%/y)

Significant differences in BFR were found between the jaws ($35.5\% \pm 9.1\%$ per year for the mandible vs $11.6\% \pm 2.0\%$ per year for the maxilla, $P = .002$) and

between the mandibular mid and maxillary posterior ($40.72\% \pm 15.43\%$ per year vs $7.66\% \pm 3.19\%$ per year, respectively; $P = .026$) as seen in Tables 2 and 3. The BFR was significantly ($P < .018$, ANOVA) greater in the bone directly adjacent (0–1 mm) to the screw ($32.7\% \pm 7.8\%$ per year) than in the bone farther (1–4 mm) from the screw ($10.2\% \pm 2.5\%$ per

Site	Variable						
	MAR ($\mu\text{m}/\text{d}$)	BV/TV (%)	BFR (%/y)	PassTh (μm)	PrTh (μm)	EnT (μm)	BC (%)
Md Mid (n = 5)							
Mean	0.90	90.39 ^{AB}	40.72 ^A	2222.13 ^A	122.01 ^A	0.00	94.40
SE	0.27	1.23	15.43	121.58	51.27	0.00	1.34
Md Post (n = 4)							
Mean	0.65	78.48 ^A	29.04 ^{AC}	1760.98 ^{AC}	0.00 ^A	0.00	93.92
SE	0.09	3.88	8.51	161.87	0.00	0.00	1.66
Mx Mid (n = 5)							
Mean	0.64	85.21 ^A	11.94 ^{AC}	1232.77 ^C	137.15 ^{AB}	0.00	78.23
SE	0.30	2.93	3.69	192.40	62.64	0.00	8.35
Mx Post (n = 4)							
Mean	0.30	84.20 ^A	7.66 ^C	1796.58 ^{AC}	386.08 ^{BC}	34.80	89.32
SE	0.11	3.96	3.19	249.38	158.17	34.80	4.38
Palate (n = 6)							
Mean	0.96	94.13 ^{BC}	13.98 ^{AC}	1702.59 ^{AC}	270.79 ^{AB}	37.08	86.93
SE	0.48	1.24	3.48	221.40	56.94	23.55	9.98

*Sites with different superscript letters denote significant differences ($P < .05$) and are described in the "Results" section.

†MAR indicates mineral apposition rate; BV/TV, bone volume/total volume; BFR, bone formation rate; PassTh, passage thickness; PrTh, periosteal thickness; EnTh, endosteal thickness; BC, bone contact; Md, mandibular; Mid, midline; Post, posterior; Mx, maxillary.

year). The mean femoral BFR for the 7 dogs ranged from 1.24% to 3.66% per year (mean 2.5% \pm 1.82% per year).

Callus and Bone Thickness

No significant differences were noted for the between-jaw ($P > .16$) and among-site ($P > .40$) endosteal thickness (Table 3). When comparing the jaws, the maxillary periosteal thickness was greater than the mandibular periosteal thickness ($P > .03$). However, the maxillary posterior site had significantly greater ($P < .05$) periosteal thickness than did the mandibular mid and mandibular posterior sites.

The passage thickness was not significantly different ($P > .09$) when comparing by jaw (Table 2). When among-site comparisons were made, the mandibular mid site was significantly different ($P < .05$) in passage thickness from the maxillary mid site. No other significant differences were found for cortical passage thickness at other sites.

DISCUSSION

Results of this study indicate that T_6 peak pullout strengths of screws and the cortical bone thickness vary as a function of insertion site, and peak pullout strengths of the screws are directly related to cortical bone thickness. Peak pullout strengths and cortical bone thickness (Table 1) at T_6 did not significantly change ($P > .90$) from the T_0 time point reported earlier. Both studies exhibited a linear relationship between the peak pullout strength and cortical bone thickness, with the combined T_0 and T_6 data resulting in $r = 0.48$ ($P < .0001$, $n = 76$). The histological findings demonstrate bone contact with the screw and modeling

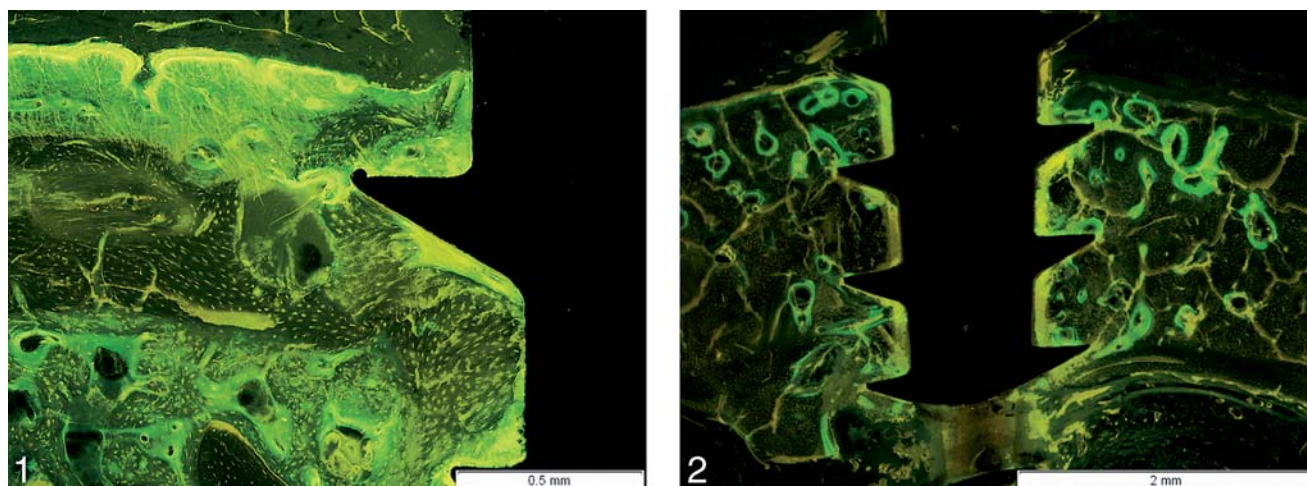
or remodeling events that are consistent with bone healing.

The experimental time period of this study (6 weeks) was driven by the interest in establishing clinical guidelines on the pullout characteristics and a description of the bone histology in the early stages of clinical use of these screws. It is thought that screws may be more vulnerable to failure during the early healing stages because of the immature interfacial bone. The present hypothesis was also based on previous histological studies reporting increased bone remodeling activity at the screw- or implant-bone interface.^{24,25} It has been demonstrated that bone within 1 mm of an implant surface exhibits a sustained elevated remodeling rate and a lower microhardness.²⁶ The elevated rate prevents the supporting bone from fully mineralizing.²⁶ Although the histological findings reflect events similar to endosseous implant healing,²⁷ barring the failures, this biological response does not result in a decrease in pullout strengths at T_6 to a level that would prevent clinical utilization of these screws.

The most significant experimental difference between the T_0 and T_6 time points is the absence of a biological response at T_0 (ie, at the time of insertion). This is highlighted by failures of the screws at various sites at T_6 . The retention at T_0 is entirely based on the strength of the bone and the design of the screw, and no such failures were recorded at T_0 . The screw failures are a clinical problem and have been reported. For example, in a clinical prospective study,¹² approximately 15 of 140 screws exfoliated over the period of their intended use. Ten failures occurred within the first month, and the remaining 5 failed after 3 to 12 months of loading.

Comparisons between the T_0 study and the T_6 study have limitations. Two sets of dogs were used at 2 different times, and although all dogs were skeletally mature and 1 to 2 years old, individual differences could exist. To maintain consistency across the studies, one operator placed all screws under similar conditions. All dogs were of the same breed, sex, and approximate weight. The screws were placed in the same region for each dog, but identical sites, orientations, and depths of penetration could not be precisely replicated during placement. This potential variation, however, is representative of what may be expected in a clinical situation. Additionally, caution must be used in directly extrapolating the results of this animal study to humans.

At the time of sacrifice, it was noted that 20 of 102 screws were loose (not anchored in bone but only by soft tissue) or were completely missing. It is not known at what point the screws became loose during the 6-week healing period. For all the screws, bone purchase was felt at the time of placement. The occlusion of the dogs did not appear to interfere with the screws, and the attending veterinary staff noted no unusual behavior (eg, pawing at the screws). It is known that primary stability and subsequent survival of screws is influenced by the quality and quantity of the bone into which they are placed.^{28,29} The majority of failures occurred in the mandibular and maxillary anterior regions. On the basis of the histology, it was concluded that a combination of thin cortical bone and small bone volume because of root proximity in this region³⁰ made placement and retention of these screws difficult. However, it is reasonable to assume that factors other than bone



FIGURES 1 and 2. FIGURE 1. Epifluorescent micrograph ($\times 100$) of screw-supporting bone in the maxillary posterior region. Note the periosteal (top) and endosteal callus, both of which have incorporated the calcein bone label. The intracortical passage is spanned by 1 pitch of the screw. FIGURE 2. Epifluorescent micrograph ($\times 40$) of screw-supporting bone in the mandibular mid region. Osteonal remodeling typical of bone healing is evident. Modeling response of the periosteal and endosteal callus is very limited. The intracortical passage is spanned by 3 pitches of the screw. Intimate bone adaptation is seen at 6 weeks postinsertion.

thickness and the biological healing response may have been responsible for the unexpectedly high failure rate in the mandibular anterior region. One potential solution would be to use a smaller-diameter (1.5 mm) screw in the mandibular anterior region; however, screws of a smaller dimension may pose a different set of problems.³¹

Pullout test results during the 2 time points suggested that no differences existed at T_0 and T_6 . Although pullout strengths were greater in the posterior mandible when compared with the maxillary anterior region, it is important to note that variables other than cortical bone thickness also may help explain the clinical success of these screws.

Histomorphometric analyses from this study can be compared with a recent study that used similar quantification methods.²⁴ In comparing the 2 studies, the higher bone contact in the present study may be attributed to the use of self-drilling screws.³² The second study reported higher MAR and consequently a higher BFR

at T_6 .²⁴ Although the researchers did not report the BFR in the dog femur, it may be possible that baseline remodeling was higher because of the younger age of the dogs. The femoral BFR values are within the normal range for turnover and indicate lack of metabolic disease that altered the remodeling rate; however, overall the results of the histomorphometric analyses were similar.

The linear measurement of cortical passage thickness is an estimate of the bone available at the various sites at time of insertion. The cortical plate thickness varied from approximately 0.8 to 2.4 mm. At some sites, only 1 thread engaged the cortical bone (Figure 1), whereas at other sites 3 threads (Figure 2) of the screw engaged the cortical bone, providing for more primary stability. Measurements of passage thickness made on the histological sections were more accurate than the measurements made after pullout (Table 1) because of the destructive nature of this test. Nonetheless, similar ranges were obtained by both methods.

It is desirable that the screws can be removed easily without the use of trephines. Thus, the screws are intentionally not subjected to surface treatments (eg, sandblasting, etching, plasma spraying) designed to increase the percentage of bone attachment. At the end of treatment, integration is easily overcome by hand removal with a surgical driver. For this reason, primary stability is critically important for early survival.³³

The ability to utilize implant and screw anchorage has greatly affected the clinical practice of orthodontics. At T_6 , peak pullout strengths of monocortical screws and the cortical bone thickness surrounding the screws varied among the regions in the canine maxilla and mandible. No significant change in pullout strength was found for T_6 compared with T_0 . The results of this study provide the clinical orthodontist with an estimate of the holding power of these screws as a function of cortical bone purchase. After correction for load orientation,¹⁸ a static holding power of approximately 122 N (95% CI, 93–150 N)

