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A. Gracco, et. al., "Effects of thread shape on the pullout strength of miniscrews", American Journal of Orthodontics and Dentofacial Orthopedics, Volume 142, Issue 2.
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11. A.Gracco, et. al., "Effects of thread shape on the pullout strength of miniscrews" was published in the American Journal of Orthodontics and Dentofacial Orthopedics, Volume 142, Issue 2 and made available on July 30, 2012. The article is currently available for public download on ScienceDirect.

12. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true.

I declare under penalty of perjury that the foregoing statements are true and correct.

Date

3/24/25

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Lindsay Allen

EXHIBIT A



American Journal of Orthodontics and Dentofacial Orthopedics

Volume 142, Issue 2, August 2012, Pages 186-190

Original article

Effects of thread shape on the pullout strength of miniscrews

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Introduction

The aim of this study was to determine the effects of variations in thread shape on the axial pullout strength of orthodontic miniscrews.

Methods

A total of 35 miniscrews, 7 of each design being considered, were tested by performing pullout tests on a synthetic bone support. We used self-tapping and self-drilling miniscrews having a diameter of 2 mm and a thread shaft length of 12 mm (the longest and the largest supplied by the manufacturer). A buttress reverse thread shape served as the control design and was tested against 4 experimental designs, each manufactured with a modification in thread shape while maintaining all other characteristics. The experimental groups had the following thread designs: buttress, 75° joint profile, rounded, and trapezoidal.

Results

The control group with a buttress reverse thread shape had consistently higher pullout strength values than did the other designs. A statistically significant reduction in pullout force was found between the buttress reverse and the buttress thread miniscrews.

Conclusions

Thread design influenced the resistance to pullout of the orthodontic miniscrews. The buttress reverse thread shape provided the greatest pullout strength.

 Previous

Next 

The group of temporary anchorage devices, also known as skeletal anchorage systems, includes screw-type implants (miniscrews, mini-implants, microscrews, and micro-implants), onplants, miniplates, zygoma implants, and palatal implants.^{1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11} With respect to other systems, miniscrews and miniplates are being progressively adopted into clinical orthodontics.¹¹ Miniscrews are generally more widely used because of their lower cost structure, ease of insertion and removal, and versatility of placement.^{12, 13, 14, 15} In clinical practice, miniscrews are loaded immediately after insertion, and achieving maximum primary stability—ie, the screw's initial holding power in the bone—is therefore of prime importance.^{16, 17, 18} Only with such stability are miniscrew micromovements reduced, thereby favoring good tissue healing, a necessary condition to maintain the device in situ.^{19, 20, 21, 22, 23}

Primary stability can be affected by various miniscrew design features, including length, diameter, thread design (shape, pitch, and depth), and self-drilling vs self-tapping threads.^{24, 25, 26, 27, 28, 29, 30, 31} Concerning thread design, little scientific evidence is available regarding the influence of thread shape on the mechanical yield of miniscrews.

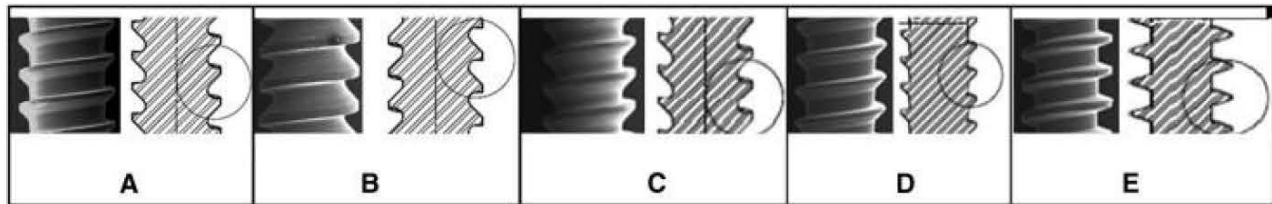
Without an established gold standard for measuring primary stability, research has been focused on the in-vitro assessment of the biomechanical properties of miniscrews as indicators for their primary stability.²⁷ Measuring performance in pullout tests with axial forces is a well-established method to compare different screw designs, and the resulting pullout strength has been described in the orthopedic, maxillofacial surgery, and orthodontic fields as a fundamental biomechanical parameter contributing to the primary stability of screws.^{31, 32, 33} The aim of this in-vitro study was to evaluate the role that variations in thread shape might have on the axial pullout strength of orthodontic miniscrews.

Material and methods

Miniscrews with 4 different experimental designs were manufactured, each with a single feature altered while maintaining all other characteristics constant compared with a commercially available control design. By hypothesizing a mean difference of 15 N (SD, 9) in the pullout strengths between the different screw designs (derived from a pilot study), with power of 80% and $\alpha = 0.05$, a minimum of 6 miniscrews was required for each group.

Seven miniscrews made of titanium grade V (Ti₆Al₄V), 12.0 mm in length and 2.0 mm in external diameter, were selected as the control (VectorTAS; Ormco, Glendora, Calif). The longest miniscrews

with the largest possible diameter offered by the manufacturer were chosen because these characteristics have been shown to provide greater resistance to pullout.^{24, 25} The aim was also to develop an experimental condition under which the greatest number of threads was available to better understand how the variations in thread design of miniscrews affect the pullout load values. The screws were self-drilling and self-tapping, with a cutting flute at their apex. They had a 15° conical shaft and an asymmetrical buttress reverse thread shape (Fig 1, A).



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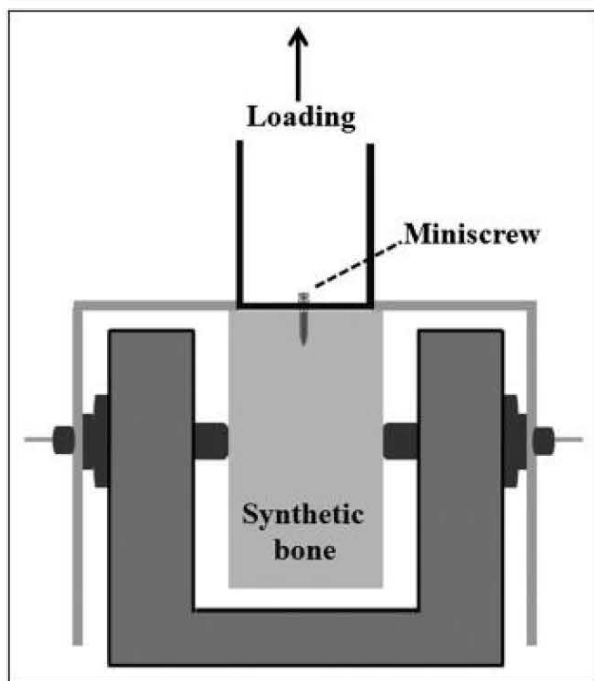
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Fig 1. Schematic illustrations of miniscrew thread-designs: **A**, buttress reverse thread shape (control); **B**, buttress thread; **C**, 75° joint profile thread; **D**, rounded thread; **E**, trapezoidal thread.

Four experimental design groups of 7 miniscrews each were made by modifying the thread shape: (1) buttress thread, opposite to the buttress reverse, with thread peaks inclined toward the miniscrew tip (Fig 1, B); (2) 75° joint profile thread, with the threads joining the shaft at an angle of 75° (Fig 1, C); (3) rounded thread, with the thread peaks rounded (Fig 1, D); and (4) trapezoidal thread, with the thread profile trapezoidal (Fig 1, E). All the other geometries of the screws were identical to the control design.

Thus, in total, 35 miniscrews were tested, 7 of each design. A synthetic bone support (1522-12 Cellular Rigid Polyurethane Foam; Sawbones Europe, Malmö, Sweden) was used to ensure uniformity in the pullout strength evaluations.³¹ On the upper surfaces of each sample, the geometric center was marked, and the miniscrews were inserted at these points to a depth corresponding to the entire thread length. Insertion was carried out through a hole (2 mm in diameter), made at the center of an appositely created steel bar (1.5 mm in thickness) bent into a U shape. The bar served as a guide for the miniscrews to be placed in a perpendicular orientation to the foam bone surface and minimized any wobbling during insertion. All procedures were performed manually by the same operator (A.G.) using a dynamometric torque driver calibrated to 15 Ncm to ensure optimal control of insertional torque.

For pullout testing, each synthetic bone support was housed securely in a frame that was fastened to a testing machine (Instron model 4467; TestResources, Shakopee, Minn) by a series of threaded bolts. This configuration of the testing setup (Fig 2) permitted a perfect axial coincidence between the miniscrew, the synthetic bone support, and the dynamometric cell. The distal ends of the steel bar were secured to the testing machine so that vertical forces, oriented parallel to the long axis of the miniscrews, were applied to the heads of the miniscrews. A crosshead speed of 10 mm per minute was chosen in accordance with previous reports.³¹



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Fig 2. Configuration of testing setup.

Statistical analysis

The pullout strength was measured as the peak force when the screw loosened from the synthetic bone support. The Levene and Lilliefors tests were used to verify the equality of variance and the normality of distribution of the examined variables. One-way analysis of variance (ANOVA) and Tukey post-hoc tests were used to compare the results obtained for each group. Statistical analyses were performed by using the statistical software (SPSS for Windows, version 16.0; SPSS, Chicago, Ill). The level of significance was set at 0.05.

Results

Since the Levene and Lilliefors tests confirmed the equality of variance and the normality of distribution of the examined variables, 1-way ANOVA was used for the between-group comparisons. A statistically significant difference was detected between the groups ($F = 4.56$; $P < 0.05$). [Table I](#) shows the means, standard deviations, and standard errors of the maximum pullout forces for each design of miniscrew. The means in the pullout tests ranged from 170.0 ± 10.3 N (buttress) to 192.8 ± 13.3 N (buttress reverse). The Tukey post-hoc test subsequently showed a statistically significant difference between the buttress reverse screw (192.8 N) and that of the buttress thread profile (170.0 N) ([Table II](#)). All other paired comparisons showed no statistically significant differences.

Table I. Means, standard deviations, standard errors, and minimum and maximum values of pullout test results

Group	n	Mean (N)	SD	SE	95% CI		Minimum (N)	Maximum (N)
					Lower limit	Upper limit		
Buttress reverse (control)	7	192.8	13.3	5.0	180.5	205.2	182.2	217.7
Buttress	7	170.0	10.3	3.9	160.5	179.6	159.3	186.0
75° joint profile	7	181.2	11.6	4.4	170.5	191.9	161.5	193.4
Rounded	7	188.4	8.7	3.3	180.4	196.5	174.4	199.6
Trapezoidal	7	184.7	8.8	3.3	176.6	192.9	173.6	197.3

Table II. Tukey test results

Groups	Mean difference	SE	Significance	95% CI	
				Lower limit	Upper limit
Buttress reverse vs buttress	22.8	5.7	0.003	6.2	39.4
Buttress reverse vs 75° joint profile	11.6	5.7	NS	-5.0	28.2
Buttress reverse vs rounded	4.4	5.7	NS	-12.2	21.0
Buttress reverse vs trapezoidal	8.1	5.7	NS	-8.5	24.7

NS, Not significant.

Discussion

The thread design of a miniscrew can vary in pitch, depth, and shape. All of these features can influence the resistance to pullout in a porous material, since the diameter, length, and screw or bone support material are constant.³⁴ The relationship between the mechanical properties of miniscrews and modifications in thread pitch and depth have been well documented. The ratio between thread depth and pitch has been expressed as a percentage (the so called “thread-shape factor”), with smaller pitch and greater depth showing greater pullout strength in porous synthetic materials and thus higher primary stability.³⁴ However, there are no reports in the orthodontic literature focusing on the influence of different thread shapes on the mechanical stability of miniscrews while controlling all other geometries.³⁵

Likewise for a dental implant, thread shape is an important parameter when designing devices that will be subjected to early loading.³⁶ Different shapes (square, V-shaped, buttress, and buttress

reverse) would allow for modifications in surface area and shear force development at the dental implant-tissue interface, therefore influencing the initial stability of the device.³⁷ The thread shapes that we examined in this study included buttress, 75° joint profile, rounded, and trapezoidal (Fig 1), which were not the same designs as commercially available orthodontic miniscrews.

In this study, the pullout tests were performed by applying vertical forces, oriented parallel to the long axis of the miniscrews.^{31, 34, 38} It is well known that, by applying pullout tests in the axial direction, the clinical situation is not realistic because it is almost impossible to load miniscrews in the axial direction in a patient.³⁸ However, these tests are widely accepted as a method for comparing different types of screws in the orthopedic, maxillofacial surgery, and orthodontic fields.^{31, 32, 33} The resulting pullout strengths provide valuable information regarding biomechanical parameters contributing to the primary stability of screws. In this study, a synthetic homogeneous material was used as a support to prevent any interference by uncontrollable variables.³⁴ The choice of foam bone allowed us to recreate under in-vitro conditions the worst possible clinical situation, in which the bone could not hold the screws firmly.

The results showed a statistically significant difference in mechanical yield between the variations in thread designs, thereby confirming that thread shape affects the miniscrew's mechanical stability.²⁸ A significant reduction in pullout force was found between the buttress reverse and the buttress thread miniscrews. This result could be explained by the geometry of the thread that was inclined toward the tip, thus reducing the resistance to removal in an axial direction. This finding was consistent with previous reports, indicating a better pullout test performance of miniscrews characterized by an asymmetrical thread design, with 45° leading and 90° trailing angles.^{38, 39, 40} Since the 75° joint profile thread showed the second highest value in terms of mean differences from the control design, it can be speculated that the magnitude of the angles of the thread might have some influence on the mechanical stability of miniscrews. Even if no statistically significant differences were detected, the buttress reverse thread devices (control design) had consistently higher pullout strength values than did the 75° joint profile, the rounded, and the trapezoidal-thread devices. Therefore, these thread profiles did adversely affect the pullout values.

Since the experimental model used in this study could not really represent the clinical environment in which the cortical bone is the main factor in miniscrew stability, more research is needed to evaluate how the different thread types perform with a cortical bone analog. Further studies by using finite element models are also required to investigate the effects of each variation in thread design on stress distribution in bone.

Conclusions

Under the experimental conditions of this in-vitro study, by using a homogeneous synthetic bone support, the thread shape did influence the resistance to pullout and, therefore, the primary stability of miniscrews. The buttress reverse thread shape (as produced by the manufacturer) had consistently higher pullout strength values than did the other designs. A statistically significant difference was

found between the buttress reverse and the buttress thread profile, with the buttress thread providing less pullout resistance than the buttress reverse; the 75° joint profile, rounded, and trapezoidal thread designs adversely affected the pullout values.

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Effects of thread shape on the pullout strength of miniscrews

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Introduction: The aim of this study was to determine the effects of variations in thread shape on the axial pullout strength of orthodontic miniscrews. **Methods:** A total of 35 miniscrews, 7 of each design being considered, were tested by performing pullout tests on a synthetic bone support. We used self-tapping and self-drilling miniscrews having a diameter of 2 mm and a thread shaft length of 12 mm (the longest and the largest supplied by the manufacturer). A buttress reverse thread shape served as the control design and was tested against 4 experimental designs, each manufactured with a modification in thread shape while maintaining all other characteristics. The experimental groups had the following thread designs: buttress, 75° joint profile, rounded, and trapezoidal. **Results:** The control group with a buttress reverse thread shape had consistently higher pullout strength values than did the other designs. A statistically significant reduction in pullout force was found between the buttress reverse and the buttress thread miniscrews. **Conclusions:** Thread design influenced the resistance to pullout of the orthodontic miniscrews. The buttress reverse thread shape provided the greatest pullout strength. (Am J Orthod Dentofacial Orthop 2012;142:186-90)

The group of temporary anchorage devices, also known as skeletal anchorage systems, includes screw-type implants (miniscrews, mini-implants, microscrews, and micro-implants), onplants, miniplates, zygoma implants, and palatal implants.¹⁻¹¹ With respect to other systems, miniscrews and miniplates are being progressively adopted into clinical orthodontics.¹¹ Miniscrews are generally more widely used because of their lower cost structure, ease of insertion and removal, and versatility of placement.¹²⁻¹⁵ In clinical practice, miniscrews are loaded immediately after insertion, and achieving maximum primary stability—ie, the screw's initial holding power in the bone—is therefore of prime

importance.¹⁶⁻¹⁸ Only with such stability are miniscrew micromovements reduced, thereby favoring good tissue healing, a necessary condition to maintain the device in situ.¹⁹⁻²³

Primary stability can be affected by various miniscrew design features, including length, diameter, thread design (shape, pitch, and depth), and self-drilling vs self-tapping threads.²⁴⁻³¹ Concerning thread design, little scientific evidence is available regarding the influence of thread shape on the mechanical yield of miniscrews.

Without an established gold standard for measuring primary stability, research has been focused on the in-vitro assessment of the biomechanical properties of miniscrews as indicators for their primary stability.²⁷ Measuring performance in pullout tests with axial forces is a well-established method to compare different screw designs, and the resulting pullout strength has been described in the orthopedic, maxillofacial surgery, and orthodontic fields as a fundamental biomechanical parameter contributing to the primary stability of screws.³¹⁻³³ The aim of this in-vitro study was to evaluate the role that variations in thread shape might have on the axial pullout strength of orthodontic miniscrews.

MATERIAL AND METHODS

Miniscrews with 4 different experimental designs were manufactured, each with a single feature altered while maintaining all other characteristics constant

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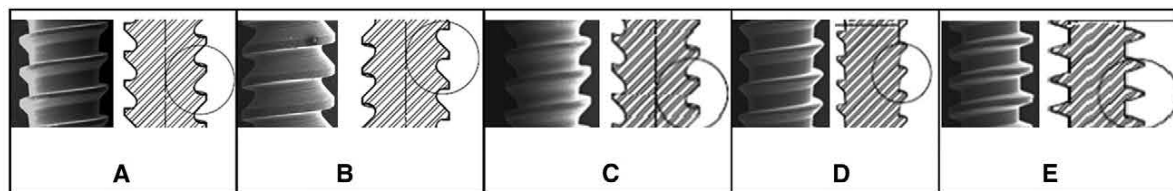


Fig 1. Schematic illustrations of miniscrew thread-designs: **A**, buttress reverse thread shape (control); **B**, buttress thread; **C**, 75° joint profile thread; **D**, rounded thread; **E**, trapezoidal thread.

compared with a commercially available control design. By hypothesizing a mean difference of 15 N (SD, 9) in the pullout strengths between the different screw designs (derived from a pilot study), with power of 80% and $\alpha = 0.05$, a minimum of 6 miniscrews was required for each group.

Seven miniscrews made of titanium grade V ($\text{Ti}_6\text{Al}_4\text{V}$), 12.0 mm in length and 2.0 mm in external diameter, were selected as the control (VectorTAS; Ormco, Glendora, Calif). The longest miniscrews with the largest possible diameter offered by the manufacturer were chosen because these characteristics have been shown to provide greater resistance to pullout.^{24,25} The aim was also to develop an experimental condition under which the greatest number of threads was available to better understand how the variations in thread design of miniscrews affect the pullout load values. The screws were self-drilling and self-tapping, with a cutting flute at their apex. They had a 15° conical shaft and an asymmetrical buttress reverse thread shape (Fig 1, A).

Four experimental design groups of 7 miniscrews each were made by modifying the thread shape: (1) buttress thread, opposite to the buttress reverse, with thread peaks inclined toward the miniscrew tip (Fig 1, B); (2) 75° joint profile thread, with the threads joining the shaft at an angle of 75° (Fig 1, C); (3) rounded thread, with the thread peaks rounded (Fig 1, D); and (4) trapezoidal thread, with the thread profile trapezoidal (Fig 1, E). All the other geometries of the screws were identical to the control design.

Thus, in total, 35 miniscrews were tested, 7 of each design. A synthetic bone support (1522-12 Cellular Rigid Polyurethane Foam; Sawbones Europe, Malmö, Sweden) was used to ensure uniformity in the pullout strength evaluations.³¹ On the upper surfaces of each sample, the geometric center was marked, and the miniscrews were inserted at these points to a depth corresponding to the entire thread length. Insertion was carried out through a hole (2 mm in diameter), made at the center of an appositely created steel bar (1.5 mm in thickness) bent into a U shape. The bar served as a guide for the miniscrews to be placed in a perpendicular orientation

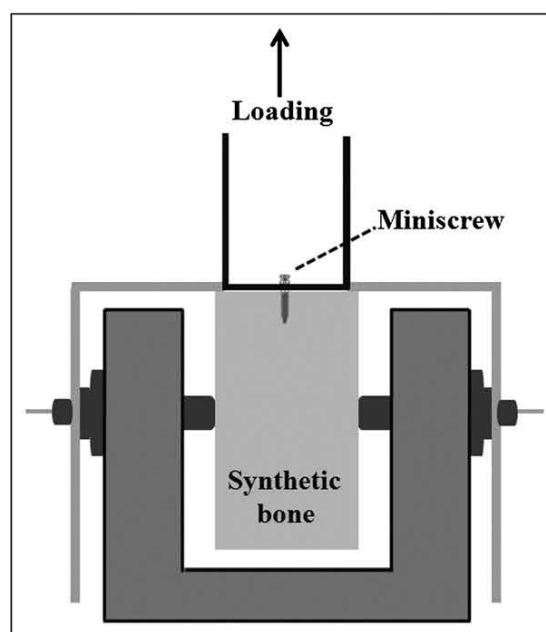


Fig 2. Configuration of testing setup.

to the foam bone surface and minimized any wobbling during insertion. All procedures were performed manually by the same operator (A.G.) using a dynamometric torque driver calibrated to 15 Ncm to ensure optimal control of insertional torque.

For pullout testing, each synthetic bone support was housed securely in a frame that was fastened to a testing machine (Instron model 4467; TestResources, Shakopee, Minn) by a series of threaded bolts. This configuration of the testing setup (Fig 2) permitted a perfect axial coincidence between the miniscrew, the synthetic bone support, and the dynamometric cell. The distal ends of the steel bar were secured to the testing machine so that vertical forces, oriented parallel to the long axis of the miniscrews, were applied to the heads of the miniscrews. A crosshead speed of 10 mm per minute was chosen in accordance with previous reports.³¹

Table I. Means, standard deviations, standard errors, and minimum and maximum values of pullout test results

Group	n	Mean (N)	SD	SE	95% CI		Minimum (N)	Maximum (N)
					Lower limit	Upper limit		
Buttress reverse (control)	7	192.8	13.3	5.0	180.5	205.2	182.2	217.7
Buttress	7	170.0	10.3	3.9	160.5	179.6	159.3	186.0
75° joint profile	7	181.2	11.6	4.4	170.5	191.9	161.5	193.4
Rounded	7	188.4	8.7	3.3	180.4	196.5	174.4	199.6
Trapezoidal	7	184.7	8.8	3.3	176.6	192.9	173.6	197.3

Table II. Tukey test results

Groups	Mean difference	SE	Significance	95% CI	
				Lower limit	Upper limit
Buttress reverse vs buttress	22.8	5.7	0.003	6.2	39.4
Buttress reverse vs 75° joint profile	11.6	5.7	NS	-5.0	28.2
Buttress reverse vs rounded	4.4	5.7	NS	-12.2	21.0
Buttress reverse vs trapezoidal	8.1	5.7	NS	-8.5	24.7

NS, Not significant.

Statistical analysis

The pullout strength was measured as the peak force when the screw loosened from the synthetic bone support. The Levene and Lilliefors tests were used to verify the equality of variance and the normality of distribution of the examined variables. One-way analysis of variance (ANOVA) and Tukey post-hoc tests were used to compare the results obtained for each group. Statistical analyses were performed by using the statistical software (SPSS for Windows, version 16.0; SPSS, Chicago, Ill). The level of significance was set at 0.05.

RESULTS

Since the Levene and Lilliefors tests confirmed the equality of variance and the normality of distribution of the examined variables, 1-way ANOVA was used for the between-group comparisons. A statistically significant difference was detected between the groups ($F = 4.56$; $P < 0.05$). Table I shows the means, standard deviations, and standard errors of the maximum pullout forces for each design of miniscrew. The means in the pullout tests ranged from 170.0 ± 10.3 N (buttress) to 192.8 ± 13.3 N (buttress reverse). The Tukey post-hoc test subsequently showed a statistically significant difference between the buttress reverse screw (192.8 N) and that of the buttress thread profile (170.0 N) (Table II). All other paired comparisons showed no statistically significant differences.

DISCUSSION

The thread design of a miniscrew can vary in pitch, depth, and shape. All of these features can influence the resistance to pullout in a porous material, since the

diameter, length, and screw or bone support material are constant.³⁴ The relationship between the mechanical properties of miniscrews and modifications in thread pitch and depth have been well documented. The ratio between thread depth and pitch has been expressed as a percentage (the so called "thread-shape factor"), with smaller pitch and greater depth showing greater pullout strength in porous synthetic materials and thus higher primary stability.³⁴ However, there are no reports in the orthodontic literature focusing on the influence of different thread shapes on the mechanical stability of miniscrews while controlling all other geometries.³⁵

Likewise for a dental implant, thread shape is an important parameter when designing devices that will be subjected to early loading.³⁶ Different shapes (square, V-shaped, buttress, and buttress reverse) would allow for modifications in surface area and shear force development at the dental implant-tissue interface, therefore influencing the initial stability of the device.³⁷ The thread shapes that we examined in this study included buttress, 75° joint profile, rounded, and trapezoidal (Fig 1), which were not the same designs as commercially available orthodontic miniscrews.

In this study, the pullout tests were performed by applying vertical forces, oriented parallel to the long axis of the miniscrews.^{31,34,38} It is well known that, by applying pullout tests in the axial direction, the clinical situation is not realistic because it is almost impossible to load miniscrews in the axial direction in a patient.³⁸ However, these tests are widely accepted as a method for comparing different types of screws in the orthopedic, maxillofacial surgery, and orthodontic fields.³¹⁻³³ The resulting pullout strengths provide valuable information

regarding biomechanical parameters contributing to the primary stability of screws. In this study, a synthetic homogeneous material was used as a support to prevent any interference by uncontrollable variables.³⁴ The choice of foam bone allowed us to recreate under in-vitro conditions the worst possible clinical situation, in which the bone could not hold the screws firmly.

The results showed a statistically significant difference in mechanical yield between the variations in thread designs, thereby confirming that thread shape affects the miniscrew's mechanical stability.²⁸ A significant reduction in pullout force was found between the buttress reverse and the buttress thread miniscrews. This result could be explained by the geometry of the thread that was inclined toward the tip, thus reducing the resistance to removal in an axial direction. This finding was consistent with previous reports, indicating a better pullout test performance of miniscrews characterized by an asymmetrical thread design, with 45° leading and 90° trailing angles.³⁸⁻⁴⁰ Since the 75° joint profile thread showed the second highest value in terms of mean differences from the control design, it can be speculated that the magnitude of the angles of the thread might have some influence on the mechanical stability of miniscrews. Even if no statistically significant differences were detected, the buttress reverse thread devices (control design) had consistently higher pullout strength values than did the 75° joint profile, the rounded, and the trapezoidal-thread devices. Therefore, these thread profiles did adversely affect the pullout values.

Since the experimental model used in this study could not really represent the clinical environment in which the cortical bone is the main factor in miniscrew stability, more research is needed to evaluate how the different thread types perform with a cortical bone analog. Further studies by using finite element models are also required to investigate the effects of each variation in thread design on stress distribution in bone.

CONCLUSIONS

Under the experimental conditions of this in-vitro study, by using a homogeneous synthetic bone support, the thread shape did influence the resistance to pullout and, therefore, the primary stability of miniscrews. The buttress reverse thread shape (as produced by the manufacturer) had consistently higher pullout strength values than did the other designs. A statistically significant difference was found between the buttress reverse and the buttress thread profile, with the buttress thread providing less pullout resistance than the buttress reverse; the 75° joint profile, rounded, and trapezoidal thread designs adversely affected the pullout values.

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