

{DESCRIPTION}

{Title of Invention}

BONE PLATE AND BONE PLATE SYSTEM

{Technical Field}

{0001}

The present invention relates to a bone plate and a bone plate system.

{Background Art}

{0002}

As a bone plate that secures portions of a broken long bone, including the femur or tibia, there is a known strip-shaped bone plate that has screw holes that are fastened to male screws provided at head portions of a plurality of screws that are fastened to the long bone (for example, see Patent Literature 1).

{0003}

In the case in which the bone plate of Patent Literature 1 is used in high tibial osteotomy of knee osteoarthritis, a cut made on an inner surface of the tibia is opened; a wedge-shaped artificial bone is inserted thereinto; the bone plate is placed at an anterior inner position of the tibia so as to bridge the cut and so as to avoid soft tissue connected to the tibia, such as medial collateral ligament or the like; and the bone plate is secured to the tibia by means of screws on either side of the cut. At this time, the two portions

separated by the cut are supported at three points, namely, a hinge portion positioned on an outer side of the tibia, the artificial bone positioned rearward on an inner side, and the bone plate positioned at the anterior inner side.

{Citation List}

{Patent Literature}

{0004}

{PTL 1} Publication of Japanese Patent No. 5230697

{Summary of Invention}

{Technical Problem}

{0005}

With the bone plate of Patent Literature 1, because a longitudinally long portion that is secured to an oblique anterior inner surface of the tibia below the cut along the longitudinal direction of the tibia and a transverse portion that is secured to an oblique anterior inner surface of the tibia above the cut are placed along substantially the same plane, the bone plate is bent so as to lean rearward when a vertical load is exerted to the joint in an upright state, and thus, there are conceivable problems such as dislodging of the artificial bone inserted in the cut or bone healing in the bent state.

{0006}

The present invention has been conceived in light of the above-described circumstances, and an object thereof is to

provide a bone plate and a bone plate system with which it is possible to prevent dislodging of an artificial bone and an increase in retroversion angle of a joint surface, even if a vertical load is exerted on a joint in an upright state after surgery.

{Solution to Problem}

{0007}

An aspect of the present invention is a bone plate including: a strip-shaped main-body portion that is secured, along a longitudinal direction of a tibia, to an oblique anterior inner surface of the tibia below a cut formed in an inner surface of the tibia; a transverse portion that is secured to an inner surface of the tibia above the cut along a direction that intersects the longitudinal direction of the tibia; and a joining portion that joins the main-body portion and the transverse portion, wherein the transverse portion and the main-body portion are provided with a plurality of screw holes that are arrayed with spaces between each other and that pass therethrough in plate-thickness directions.

{0008}

With this aspect, when the strip-shaped main-body portion is placed, along the longitudinal direction of the tibia, at the oblique anterior inner surface of the tibia below the cut formed in the inner surface of the tibia, the transverse portion is placed at a position extending along the inner

surface of the tibia above the cut. It is possible to hold the opened cut by individually securing the main-body portion and the transverse portion to the tibia on either side of the cut by using the screws fastened to the screw holes.

{0009}

In this case, because the main-body portion and the transverse portion that are joined by the joining portion are respectively secured to the oblique anterior inner surface and the inner surface of the tibia in a twisted manner, it is possible to prevent the bone plate from bending and collapsing, even if a vertical load is exerted to the joint in an upright state, as does happen with a conventional bone plate that is secured along substantially the same plane. As a result, it is possible to prevent dislodging of the artificial bone that is inserted into the cut and bone healing in a retroverted state.

{0010}

In the above-described aspect, the main-body portion, the joining portion, and the transverse portion may have a continuous curved-surface shape so as to be twisted about an axis parallel to the longitudinal axis of the main-body portion.

By doing so, when the bone plate is placed at a side surface of the tibia, the bone plate is placed so as to conform to the side-surface shape of the tibia, and thus, the

bone plate does not become a hindrance by greatly protruding when subcutaneously implanted.

{0011}

In addition, another aspect of the present invention is a bone plate system including: any one of the above-described bone plates; and screws that have head portions including first male screws to be fastened to the screw holes of the bone plate, that have threaded portions including second male screws to be fastened to the tibia, and that secure the bone plate to the tibia.

{0012}

With this aspect, the bone plate is placed at an upper side surface of the tibia; the screws are individually made to pass through the plurality of screw holes that are provided in the main-body portion and the transverse portion, respectively; the threaded portions having the second male screws are fastened to the tibia; and, finally, the head portions having the first male screws are fastened to the screw holes; and thus, it is possible to hold the cut in an open state by reliably securing the bone plate to the tibia on either side of the cut.

{0013}

In the above-described aspect, the screws to be fastened to the screw holes provided in the main-body portion may be fastened in an oblique lateral direction from an oblique

anterior inner side of the tibia toward an oblique posterior outer side thereof, and the screws to be fastened to the screw holes provided in the transverse portion may be fastened nearly in the lateral direction from the inner surface of the tibia toward an outer surface thereof.

{0014}

By doing so, the screws are fastened to the tibia closer to the joint surface located above the cut in nearly the lateral direction toward the outer surface from the inner surface of the tibia by utilizing the screw holes of the transverse portion placed at the inner surface. In the case of the related art in which a bone plate is secured to an oblique anterior inner surface of the tibia, screws must be diagonally fastened toward the oblique posterior outer surface from the oblique anterior inner surface, and, in the case in which the bone quality is poor, it is not only impossible to achieve sufficient securing forces but the screws also move in the cancellous bone in some cases, thus cutting the cancellous bone. As compared with this, by fastening the screws nearly in the lateral direction in which the lateral cross-sectional dimension of the tibia is large, it is possible to employ longer screws, and thus, it is possible to maintain the health of the cancellous bone by achieving high securing forces.

{0015}

In addition, in the above-described aspect, when

projected onto a joint surface of the tibia, the screws to be fastened to the screw holes provided in the main-body portion and the screws to be fastened to the screw holes provided in the transverse portion may intersect each other in an area that occupies 50 % to 80 % of the total length of the tibia from the inner surface to the joint surface.

{0016}

When loads from the femur are exerted on the joint in an upright state after surgery, the centers of resultant forces of the loads projected onto the joint surface of the tibia are generally placed at positions occupying 60 % or more of the total length of the tibia from the inner surface to the joint surface. Doing so facilitates capturing of the loads exerted on the tibia from the femur by using the bone plate.

{0017}

In addition, in the above-described aspect, the screws may be hollow screws having through-holes through which guide pins can pass.

Because the main-body portion and the transverse portion are placed in a twisted manner, the fastening directions of the screws are not uniform, and thus, the securing directions of the screws tend to be mistaken even if preparation holes are provided.

By doing so, by utilizing the through-holes provided in the screws, it is possible to fasten the screws by using the

guide pins inserted into preparation holes in advance as guides, and thus, it is possible to enhance the workability of the fastening procedure.

{0018}

In addition, the above-described aspect may be provided with a wedge-shaped artificial bone member that is inserted into the cut, wherein top and bottom surfaces of the artificial bone member that come into contact with cut surfaces of the cut may be inclined in one direction in the width direction so that the thickness of the artificial bone member gradually decreases.

By doing so, it is possible to facilitate making the top and bottom surfaces of the artificial bone member fit with the cut surfaces of the cut in the tibia.

{Advantageous Effects of Invention}

{0019}

The present invention affords an advantage in that it is possible to prevent dislodging of an artificial bone and an increase in retroversion angle of a joint surface, even if a vertical load is exerted on a joint in an upright state after surgery.

{Brief Description of Drawings}

{0020}

{Fig. 1} Fig. 1 is a diagram showing the entirety of a bone plate system according to an embodiment of the present

invention.

{Fig. 2A} Fig. 2A is a front view showing a bone plate according to the embodiment of the present invention, which is to be used in the bone plate system in Fig. 1.

{Fig. 2B} Fig. 2B is a side view showing the bone plate in Fig. 2A.

{Fig. 2C} Fig. 2C is a plan view showing the bone plate in Fig. 2A.

{Fig. 3} Fig. 3 is a partial longitudinal cross-sectional view showing the relationship between screws and screw holes provided in the bone plate in Fig. 2A.

{Fig. 4} Fig. 4 is a diagram in which the arrangement of the screws in the bone plate system in Fig. 1 is projected onto a joint surface.

{Fig. 5} Fig. 5 is a perspective view showing an example artificial bone to be used in the bone plate system in Fig. 1.

{Fig. 6} Fig. 6 is a diagram showing the arrangement of the screws secured to a transverse portion of the bone plate in the bone plate system in Fig. 1.

{Fig. 7} Fig. 7 is a diagram showing the arrangement of screws in a conventional bone plate system shown as a comparative example for Fig. 6.

{Fig. 8} Fig. 8 is a diagram of an artificial bone that is used in the bone plate system in Fig. 1, as viewed from an inner surface side of a tibia.

{Fig. 9} Fig. 9 is a longitudinal cross-sectional view showing screws that are used in a modification of the bone plate system in Fig. 1.

{Fig. 10} Fig. 10 is a diagram for explaining the procedure for fastening the screws in Fig. 9 by using guide pins.

{Fig. 11} Fig. 11 is a diagram showing a modification of the artificial bone in Fig. 8.

{Description of Embodiment}

{0021}

A bone plate 1 and a bone plate system 2 according to an embodiment of the present invention will be described below with reference to the drawings.

As shown in Fig. 1, the bone plate system 2 according to this embodiment is provided with: the bone plate 1; a plurality of screws 3 for securing the bone plate 1 to an upper side surface of a tibia X; and an artificial bone 4 that is inserted into a cut formed outward in the tibia X from an inner-surface side thereof.

{0022}

The bone plate 1 according to this embodiment is a long, thin strip-shaped member that is secured to an upper side surface of the tibia X after performing osteotomy in high tibial osteotomy of knee osteoarthritis, and has a subtle curved shape in accordance with the typical surface shape so that the bone plate 1 can be made to conform to the curved

surface shape of a side surface of the tibia X at a position at which the shaft portion of the tibia X shifts toward an end portion thereof.

{0023}

As shown in Figs. 2A, 2B, and 2C, this bone plate 1 is formed in substantially a T-shape as a whole and is provided with: a long, thin strip-shaped main-body portion 1a; a transverse portion 1b that extends in a direction that intersects the longitudinal direction of the main-body portion 1a; and a joining portion 1c that joins the main-body portion 1a and the transverse portion 1b. The joining portion 1c is bent in one direction from one end of the main-body portion 1a and has a twisted shape (with a twist angle of 10° to 25°) about the longitudinal axis of the main-body portion 1a toward the transverse portion 1b at the tip thereof. By doing so, the joining portion 1c is arranged so that the main-body portion 1a and the transverse portion 1b can be made parallel to planes that intersect each other.

{0024}

The main-body portion 1a of the bone plate 1 is provided with a plurality of screw holes 5 with spaces therebetween in the longitudinal direction thereof. In addition, the transverse portion 1b is provided with a plurality of, for example, three, screw holes 6 with spaces therebetween in a direction that intersects the longitudinal direction of the

main-body portion 1a and one screw hole 7 with spaces relative to the screw holes 5 and 6 in the aforementioned longitudinal direction.

As shown in Fig. 3, these screw holes 5, 6, and 7 are tapered screw holes and have inner diameters that gradually decrease from one side to the other side in the plate-thickness direction, that is, toward the side that is made to face the tibia X. Note that, although the case of the screw hole 5 of the main-body portion 1a is shown as an example in Fig. 3, the configurations of the screw holes 6 and 7 of the transverse portion 1b and the joining portion 1c are the same.

{0025}

As shown in Figs. 1 and 3, the screws 3 are formed in long, thin circular-rod shapes and are provided with threaded portions 8 that have, on the outer circumferential surfaces thereof, bone-securing male threaded portions (second male screws) 8a to be fastened to preparation holes (not shown) formed in the tibia X and head portions 10 provided with tapered screws (first male screws) 9 to be fastened to the screw holes 5, 6, and 7 of the bone plate 1.

{0026}

Because the main-body portion 1a and the transverse portion 1b are placed at mutually twisted positions when the tapered screws 9 of the head portions 10 of the screws 3 are fastened to the screw holes 5 formed in the main-body portion

1a of the bone plate 1 and the screw holes 6 formed in the transverse portion 1b thereof, as shown in Fig. 4, the screws 3, when projected onto the joint surface, are configured to be fastened so as to intersect each other. These intersecting positions of the screws 3 are placed in an area occupying 50 % to 80 % of the total width of the tibia X from the inner surface to the joint surface in the lateral direction.

{0027}

As shown in Fig. 5, the artificial bone 4 is formed of a calcium-phosphate-based ceramic and is formed in substantially a wedge-like block shape. More specifically, in the artificial bone 4, at least one of the surfaces (top and bottom surfaces) that come into contact with cut surfaces Y of the tibia X when inserted into the cut is formed of an inclined surface in which the thickness thereof gradually decreases along one direction in the longitudinal direction and one direction in the width direction. Fig. 5 shows an example in which the top and bottom surfaces are both formed of the inclined surfaces.

{0028}

The operation of the thus-configured bone plate 1 and bone plate system 2 according to this embodiment will be described below.

In order to perform high tibial osteotomy of knee osteoarthritis by using the bone plate system 2 according to

this embodiment, a cut is formed outward from an inner surface of the tibia X in a direction inclined with respect to the longitudinal axis of the tibia X, and the cut surfaces Y are separated by using predetermined equipment. Then, as shown in Fig. 1, when the main-body portion 1a of the bone plate 1 is placed at an oblique anterior inner surface of the tibia X in the state in which the wedge-shaped artificial bone 4 is inserted between the separated cut surfaces Y, because the joining portion 1c bridges the cut and the transverse portion 1b is placed at a joint-surface-side inner surface of the tibia X, the preparation holes are formed inside the individual screw holes 5, 6, and 7 of the main-body portion 1a and the transverse portion 1b.

{0029}

At this time, the preparation holes are formed along the axial directions of the individual screw holes 5, 6, and 7. Then, the male threaded portions 8a of the screws 3 are fastened to the preparation holes after being made to pass through the individual screw holes 5, 6, and 7, and, finally, the tapered screws 9 provided in the head portions 10 of the screws 3 are fastened to the screw holes 5, 6, and 7.

{0030}

By doing so, the bone plate 1 is secured to the tibia X in a state in which the bone plate 1 is placed along the surface of the tibia X. Because the individual screw holes 5,

6, and 7 and the first male screws 9 of the head portions 10 of the screws 3 are formed of the tapered screws, securing forces are increased as fastening proceeds, and thus, it is possible to more reliably secure the bone plate 1 to the surface of the tibia X.

{0031}

Then, the wedge-shaped artificial bone 4 is subsequently inserted into the cut. By doing so, a vertical load exerted in the direction that closes the cut can be supported by the tibia X above and below the opened cut at three points, namely, at a hinge portion 11 provided on the outside, the bone plate 1 secured from the oblique anterior inner surface to the inner surface, bridging the cut, and the artificial bone 4 sandwiched between the cut surfaces Y.

{0032}

In this case, with the bone plate 1 according to this embodiment, the main-body portion 1a and the transverse portion 1b that are secured to the tibia X, bridging the cut, are placed at mutually twisted positions by the joining portion 1c, and thus, the main-body portion 1a is secured to the oblique anterior inner surface of the tibia X, whereas the transverse portion 1b is secured to the inner surface of the tibia X. As a result, even if a vertical load acts on the tibia X from the femur via the joint surface of a patient standing upright after surgery, it is possible to prevent the

vertical load from generating a moment that bends the bone plate 1 in the plate-thickness direction.

{0033}

In other words, with a conventional bone plate 12 in which the main-body portion 1a and the transverse portion 1b are placed on substantially the same plane, a vertical load generates a moment that bends the bone plate 12 in the plate-thickness direction when the vertical load acts on the joint surface. As a result, there is a problem in that, when the bone plate 12 is bent in the plate-thickness direction, the artificial bone 4 is expelled (dislodged) from the cut, which closes the opened cut, and thus, the joint surface is inclined rearward (retroverted) and the bone is healed in this state.

{0034}

In contrast, with the bone plate 1 according to this embodiment, by twisting the joining portion 1c, because the vertical load acts between the bone plate 1 and the hinge portion 11 and is reliably received by the two points on both sides, a moment that bends the bone plate 1 in the plate-thickness direction is not generated, and thus, it is possible to more reliably prevent dislodging of the artificial bone 4 and retroversion of the joint surface.

In addition, although it is possible to achieve the same effects so long as the main-body portion 1a can be secured to the inner surface of the tibia X, because soft tissue, such as

the medial collateral ligament or the like, is connected to the tibia X below the cut, it is not possible to secure the main-body portion 1a to the inner surface of the tibia X.

{0035}

By securing the main-body portion 1a to the oblique anterior inner surface of the tibia X and by securing only the transverse portion 1b to the inner surface of the tibia X by twisting the joining portion 1c, there is an advantage in that it is possible to more reliably prevent dislodging of the artificial bone 4 and retroversion of the joint surface while avoiding the soft tissue, such as medial collateral ligament or the like.

{0036}

In addition, by placing the transverse portion 1b at the inner surface of the tibia X, the screws 3 to be secured to the transverse portion 1b are fastened so as to move laterally straight toward the hinge portion 11 across the tibia X on the joint-surface side, as shown in Fig. 6. In the related art, as shown in Fig. 7, when placing the transverse portion 1b at an oblique anterior inner surface, because the screws 3 are fastened to the tibia X in the direction of the oblique posterior outer side, the use of the screws 3 has been limited to short ones. With this embodiment, long screws 3 can be fastened to the tibia X in the portions thereof having long dimensions so as to move laterally straight thereacross. In

general, in the case in which the bone quality is poor, using the short screws 3 under unsatisfactory securing conditions causes the screws 3 to move in the cancellous bone, which sometimes cut the cancellous bone; however, by using the long screws 3, there is an advantage in that it is possible to maintain the cancellous bone in a healthy state.

{0037}

In addition, with the bone plate system 2 according to this embodiment, the screws 3 can be fastened in the oblique posterior direction with the main-body portion 1a placed at the oblique anterior inner surface of the tibia X, and the screws 3 can be fastened straight in the horizontal direction with the transverse portion 1b placed at the inner surface of the tibia X.

{0038}

According to Fig. 4, the screws 3, when projected onto the joint surface of the tibia X, intersect each other in an area occupying 50 % to 80 % of the total width from the inner surface to the joint surface of the tibia X in the lateral direction.

In the state in which the patient is standing upright, the centers of the resultant forces of loads exerted on the joint from the femur are generally placed at positions occupying 60 % or more of the total length from the inner surface to the joint surface. Therefore, by aligning the

positions at which the screws 3 intersect with the positions of the centers of the resultant forces of the loads, there is an advantage in that it is possible to facilitate capturing of the loads exerted on the tibia X from the femur by using the bone plate 1.

{0039}

In addition, because the artificial bone 4 is not only formed in a wedge shape in which the size thereof decreases toward the tip in the longitudinal direction but also has an inclined surface in which the thickness thereof decreases in one direction also in the width direction, the bone plate system 2 according to this embodiment affords the following advantages.

Specifically, because the size of the artificial bone 4 decreases toward the tip along the longitudinal direction, by inserting, from the inner-surface side, the wedge-shaped artificial bone 4 into the cut formed in a shape that, by being opened, expands toward an opening end on the inner-surface side, it is possible to bring the top and bottom surfaces of the artificial bone 4 into close contact with the cut surfaces Y above and below.

{0040}

Furthermore, with the artificial bone 4 in this embodiment, because at least one of the top and bottom surfaces thereof is inclined so that the thickness decreases

in one direction also in the width direction, in the state in which the artificial bone 4 is inserted into the cut, it is possible to place the artificial bone 4 so that the thickness thereof becomes large rearward and low forward, as shown in Fig. 8. By doing so, even if a vertical load acts on the tibia X from the femur via the joint surface of a patient standing upright after surgery, it is possible to prevent retroversion of the joint surface, and it is also possible to more reliably bring the top and bottom surfaces of the artificial bone 4 into close contact with both of the cut surfaces Y.

{0041}

Note that, in this embodiment, as shown in Fig. 9, hollow screws 3 that have through-holes 13 through which guide pins 14 can pass may be employed as the screws 3.

As shown in Fig. 4, because the main-body portion 1a and the transverse portion 1b of the bone plate 1 are placed in different planes by twisting the joining portion 1c, the fastening directions of the screws 3 are not uniform, and thus, the securing directions of the screws 3 are easily mistaken even if preparation holes are provided in the tibia X. By doing so, there is an advantage in that, as shown in Fig. 10, by utilizing the through-holes 13 provided in the screws 3, it is possible to fasten the screws 3 by using the guide pins 14 inserted into preparation holes 15 in advance as

guides, and thus, it is possible to enhance the workability of the fastening procedure.

{0042}

In addition, in this embodiment, as shown in Fig. 5, it is preferable that the dimensions of the wedge-shaped artificial bone 4 be set as below:

$$|\theta| - |A| \leq \pm 1.5,$$

$$5 \leq A \leq 20 \text{ mm},$$

$$5 \leq B \leq 20 \text{ mm}, \text{ and}$$

$$10 \leq C \leq 50 \text{ mm},$$

where θ is the angle at the tip of the wedge shape in the artificial bone 4, A is the maximum height of the artificial bone 4, B is the width of the artificial bone 4, and C is the length of the artificial bone 4. By configuring the artificial bone to have such dimensions, it is possible to provide a wedge shape having the dimensions that fit the dimensions of the human tibia X.

{0043}

It is more preferable that the dimensions be:

$$|\theta| \approx |A|,$$

$$6 \leq A \leq 15 \text{ mm},$$

$$8 \leq B \leq 15 \text{ mm}, \text{ and}$$

$$25 \leq C \leq 50 \text{ mm}.$$

{0044}

In addition, it is preferable that the artificial bone 4 be formed of a calcium-phosphate-based ceramic having a porosity of 30 % to 80 %. Examples thereof include β TCP, α TCP, OCP, hydroxyapatite, bio-derived materials, calcium sulfate cement, and so forth.

{0045}

In addition, in this embodiment, although the artificial bone 4 has inclined surfaces both in the top and bottom surfaces thereof, alternatively, as shown in Fig. 11, only the top surface or the bottom surface may be formed as an inclined surface.

{Reference Signs List}

{0046}

1, 12 bone plate

1a main-body portion

1b transverse portion

1c joining portion

2 bone plate system

3 screw

4 artificial bone (artificial bone member)

5, 6, 7 screw hole

8 threaded portion

8a male threaded portion (second male screw)

9 tapered screw (first male screw)

10 head portion

13 through-hole

14 guide pin

X tibia

{CLAIMS}

{Claim 1}

A bone plate comprising:

a strip-shaped main-body portion that is secured, along a longitudinal direction of a tibia, to an oblique anterior inner surface of the tibia below a cut formed in an inner surface of the tibia;

a transverse portion that is secured to an inner surface of the tibia above the cut along a direction that intersects the longitudinal direction of the tibia; and

a joining portion that joins the main-body portion and the transverse portion,

wherein the transverse portion and the main-body portion are provided with a plurality of screw holes that are arrayed with spaces between each other and that pass therethrough in plate-thickness directions.

{Claim 2}

A bone plate according to Claim 1, wherein the main-body portion, the joining portion, and the transverse portion have a continuous curved-surface shape so as to be twisted about an axis parallel to the longitudinal axis of the main-body portion.

{Claim 3}

A bone plate system comprising:

a bone plate according to Claim 1 or 2; and
screws that have head portions including first male
screws to be fastened to the screw holes of the bone plate,
that have threaded portions including second male screws to be
fastened to the tibia, and that secure the bone plate to the
tibia.

{Claim 4}

A bone plate system according to Claim 3,

wherein the screws to be fastened to the screw holes
provided in the main-body portion are fastened in an oblique
lateral direction from an oblique anterior inner side of the
tibia toward an oblique posterior outer side thereof, and

the screws to be fastened to the screw holes provided in
the transverse portion are fastened nearly in the lateral
direction from the inner surface of the tibia toward an outer
surface thereof.

{Claim 5}

A bone plate system according to Claim 3 or 4, wherein, when
projected onto a joint surface of the tibia, the screws to be
fastened to the screw holes provided in the main-body portion
and the screws to be fastened to the screw holes provided in

the transverse portion intersect each other in an area that occupies 50 % to 80 % of the total length of the tibia from the inner surface to the joint surface.

{Claim 6}

A bone plate system according to any one of Claims 3 to 5, wherein the screws are hollow screws having through-holes through which guide pins can pass.

{Claim 7}

A bone plate system according to any one of Claims 3 to 6, further comprising:

 a wedge-shaped artificial bone member that is inserted into the cut,

 wherein top and bottom surfaces of the artificial bone member that come into contact with cut surfaces of the cut are inclined in one direction in the width direction so that the thickness of the artificial bone member gradually decreases.