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(54) **FASTENER INSERTION METHOD**

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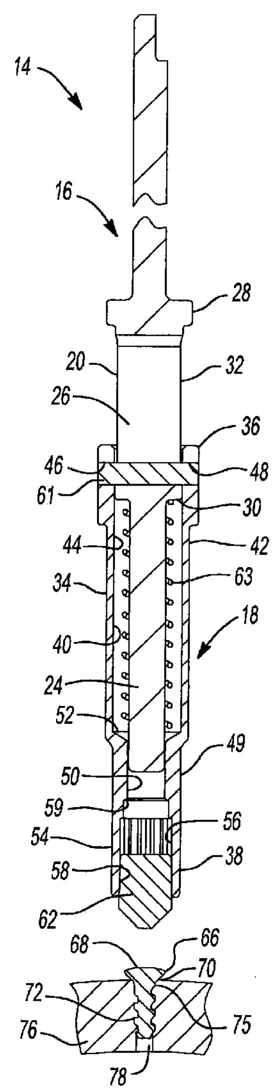
(57) **ABSTRACT**

A method may include rotating a threaded fastener at a first rotational speed to provide a kinetic energy force component for the fastener based on the first rotational speed and driving the fastener into a structure based on the rotating. The structure may provide a torsional resistance during the driving greater than a torsional strength of the fastener. The driving may provide a torque force component applied to the fastener. The driving may cut threads into the structure with the fastener. The driving may apply a total force to the structure from the fastener including the kinetic energy force component and the torque force component. The total force applied by the fastener may be greater than or equal to a force required for the cutting. The torque force component may be less than a torsional strength of the fastener.



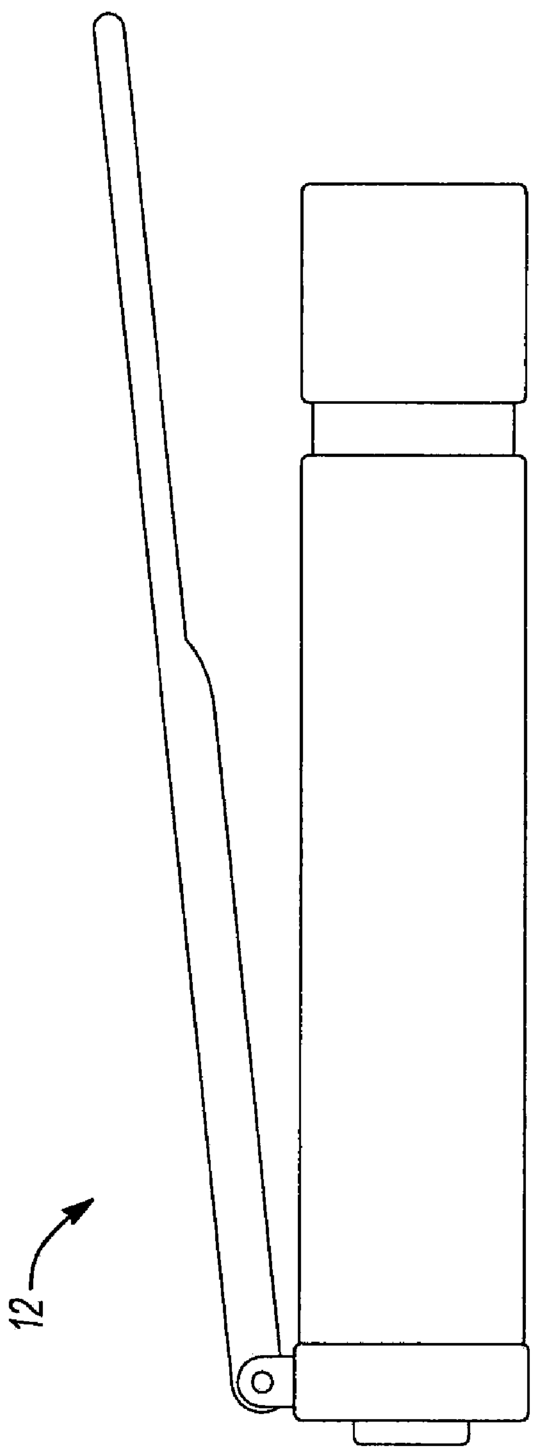


Fig-1

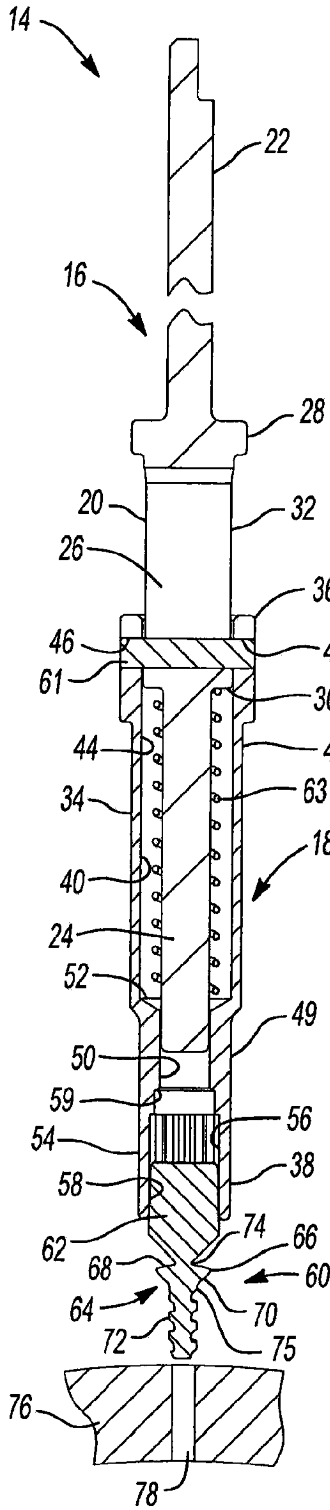

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Fig-2

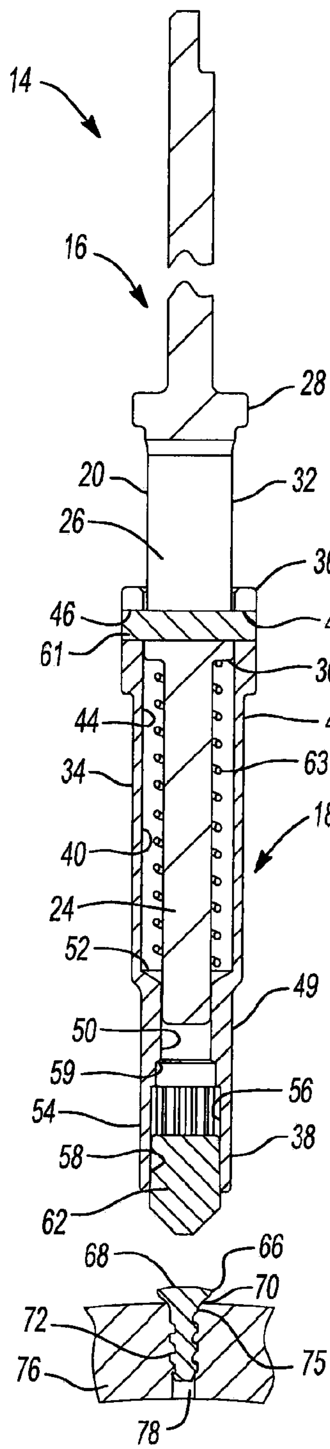
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Fig-3

FASTENER INSERTION METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/904,678, filed on Mar. 2, 2007 and U.S. Provisional Application No. 60/905,157, filed on Mar. 6, 2007. The disclosures of the above applications are incorporated herein by reference.

FIELD

[0002] The present disclosure relates to threaded fasteners, and more specifically to insertion methods for threaded fasteners.

BACKGROUND

[0003] The statements in this section merely provide background information related to the present disclosure and may not constitute prior art.

[0004] Typical fastener insertion techniques may include applying a torque to a threaded fastener to rotationally drive the fastener into a structure. The torsional strength of the fastener is typically greater than the torque applied to drive the fastener to prevent breaking of the fastener before insertion is completed. The torque applied to the fastener increases when a self-tapping fastener is used due to the additional force required to cut threads into the structure.

SUMMARY

[0005] A method may include rotating a threaded fastener at a first rotational speed to provide a kinetic energy force component for the fastener based on the first rotational speed and driving the fastener into a structure based on the rotating. The structure may providing a torsional resistance during the driving greater than a torsional strength of the fastener. The driving may provide a torque force component applied to the fastener. The driving may cut threads into the structure with the fastener. The driving may apply a total force to the structure from the fastener including the kinetic energy force component and the torque force component. The total force applied by the fastener may be greater than or equal to a force required for the cutting. The torque force component may be less than the torsional strength of the fastener.

[0006] The method may further include terminating the driving when the fastening portion is inserted a predetermined amount into the structure.

[0007] An apparatus according to the present disclosure may include a threaded fastener having a torsional strength and a driver engaged with the fastener. The driver may be adapted to drive the fastener at a first rotational speed into a structure and apply a torque force component to said fastener. The fastener may be adapted to have a kinetic energy force component based on the first rotational speed and to apply a total force to the structure including the torque force component and the kinetic energy force component. The fastener may cut threads into the structure based on the total force. The total force may be greater than or equal to a force required to cut the threads and the torque force component may be less than the torsional strength of the fastener.

[0008] Further areas of applicability will become apparent from the description provided herein. It should be understood that the description and specific examples are intended for purposes of illustration only and are not intended to limit the scope of the present disclosure.

DRAWINGS

[0009] The drawings described herein are for illustration purposes only and are not intended to limit the scope of the present disclosure in any way.

[0010] FIG. **1** is a perspective view of a powered driver according to the present disclosure;

[0011] FIG. **2** is a translucent plan view of an adapter assembly and fastener according to the present disclosure; and

[0012] FIG. **3** is an additional translucent plan view of the adapter assembly and fastener of FIG. **2**.

DETAILED DESCRIPTION

[0013] The following description is merely exemplary in nature and is not intended to limit the present disclosure, application, or uses.

[0014] With reference to FIGS. **1**-**3**, a driving assembly for a fastener may include a powered driver **12** and an adapter assembly **14**. Powered driver **12** may be any driver capable of driving adapter assembly **14** in the manner discussed below. Powered driver **12** shown in FIG. **1** is a powered driver from MicroAire Surgical Instruments L.L.C. of Charlottesville, Va. Adapter assembly **14** may be engaged with and driven by powered driver **12**.

[0015] More specifically, adapter assembly **14** may include a plunger **16** and a driving member **18**. Plunger **16** may include a central body portion **20**, a connection shank **22**, and an ejector shaft **24**. Central body portion **20** may include a generally cylindrical body **26** having first and second ends **28**, **30**. An elongate passage **32** may extend radially through cylindrical body **26** and may have an axial extent along cylindrical body **26**. Connection shank **22** may extend axially from first end **28** of cylindrical body **26** and may engage powered driver **12** for driving adapter assembly **14**. Ejector shaft **24** may be generally cylindrical or may be in the form of a drill bit for drilling a pilot hole, as discussed below, and may extend axially from second end **30** of cylindrical body **26** and may be slidably disposed within driving member **18**, as discussed below.

[0016] Driving member **18** may include an elongate body **34** having first and second ends **36**, **38**. A central opening **40** may extend axially through elongate body **34** and first and second ends **36**, **38**. A first portion **42** of elongate body **34** may include a first portion **44** of central opening **40** passing therethrough. First portion **44** of central opening **40** may extend through first end **36** and may have a first diameter greater than the diameter of a central portion of cylindrical body **26** and second end **30** thereof and less than the diameter of first end **28** of cylindrical body **26**. A set of apertures **46**, **48** may extend radially through first portion **42** of driving member **18** near first end **36**.

[0017] A second portion **49** of elongate body **34** may include a second portion **50** of central opening **40** passing therethrough. Second portion **50** of central opening **40** may have a second diameter that is less than the first diameter of first portion **44**, forming a step **52** therebetween. The second diameter of second portion **50** may be greater than the diameter of ejector shaft **24** and less than the diameter of cylindrical body **26** of plunger **16**.

[0018] A third portion **54** of elongate body **34** may include a driving geometry. More specifically, third portion **54** may include a third portion **56** of central opening **40** extending therethrough. Third portion **56** may extend through second end **38** of driving member **18** and may define a series of flats **58** or some other form of driving geometry on an inner wall of third portion **56**. Third portion **56** of central opening **40** may have a third diameter that is greater than the second diameter of second portion **50**, forming a step **59** therebetween.

[0019] Cylindrical body **26** may be disposed in first portion **44** of central opening **40** and a pin **61** may pass through apertures **46**, **48** in driving member **18** and elongate passage **32** in plunger **16**, slidably coupling plunger **16** to driving member **18**. Ejector shaft **24** may extend into first and second portions **44**, **50** of central opening **40** when plunger **16** is in a retracted position (seen in FIGS. **2** and **3**) and a may be extended into third portion **56** of central opening **40** to abut and/or eject a fastener **60**, as discussed below. A spring **63** may be engaged with step **52** and second end **30** of cylindrical body **26**, urging plunger **16** into the retracted position.

[0020] Fastener **60** may be disposed within third portion **56** of central opening **40**. Fastener **60** may include a torque limiting feature, such as first and second portions that are removable from one another when a predetermined torque limit is exceeded. For example, the first portion may include a breakaway portion **62** and the second portion may include a fastening portion **64**. Breakaway portion **62** may be coupled to fastening portion **64** and may include a series of flats engaged with flats **58** within third portion **56** of central opening **40**, providing for driving of fastener **60** by the driving assembly. Breakaway portion **62** may be retained within third portion **56** of central opening **40** through an interference fit engagement therewith. Fastening portion **64** may include a head **66** having upper and lower portions **68**, **70** and a threaded shank **72**. Breakaway portion **62** may be integrally formed with and coupled to upper portion **68** of head **66** at a reduced diameter breakaway region **74** and threaded shank **72** may extend from lower portion **70**. A series of recesses (not shown) may be formed in a perimeter of head **66**.

[0021] Fastener **60** may be formed from a variety of materials including, but not limited to metals (including titanium, titanium alloys, stainless steel, zirconium, and CoCr), biocompatible non-resorbable materials (including polyetheretherketone (PEEK) and polyetherketoneketone (PEKK)), biocompatible resorbable materials, ceramics, composite materials, allograft or xenograft (including demineralized bone matrix and coral), or combinations thereof.

[0022] The fasteners and fastener insertion method discussed below may include a variety of applications such as to craniofacial procedures, neurosurgical procedures, spinal procedures, orthopedic procedures, suture anchors (Glencord anchors), small bone fixation/anchors, anterior cruciate ligament (ACL) fixation devices (tendon repair devices), and soft tissue anchors. Further, while discussed with respect to powered driver **12**, adapter assembly **14**, and fastener **60**, it is understood that a variety of alternate driving assemblies and fasteners may be used as well.

[0023] As seen in FIGS. **2** and **3**, fastener **60** may be fixed to another structure **76** such as bone, wood, or some other media. A pilot hole **78** may be drilled into structure **76** and fastener **60** may be inserted into pilot hole **78**. More specifically, fastener **60** may cut threads into pilot hole **78**. Fastener **60** may therefore act as a self tapping screw. In order to insert a self-tapping screw, work is performed on the screw. Work is generally defined as a force imparted over a distance:

$$\text{Work}=F_i \times D;$$

where F_i is force and D is distance.

[0024] In the context of the present disclosure, the force (F_i) noted above in the work definition may generally include a sum of the force (F_c) needed to cut (or tap) threads and the force of friction (F_{f1}) from the threads on structure **76**. The driving assembly may apply the force (F_i) to fastener **60** in order to insert fastener **60** into pilot hole **78**. The force (F_s) applied by fastener **60** may generally include the sum of the force (F_t) from the torque imparted on fastener **60** and the force (F_k) from the kinetic energy of fastener **60**. Therefore, in order to insert fastener **60** into structure **76**, force (F_s) should be greater than force (F_i). When fastener **60** is inserted at low rotational speeds, the kinetic energy force component (F_k) may be small relative to the torque force component (F_t).

[0025] Kinetic energy is generally defined as:

$$K=\tfrac{1}{2}I\omega^2;$$

where K is kinetic energy, I is moment of inertia, and ω is angular rotational velocity. Angular rotational velocity is directly proportional to rotational speed. Therefore, the kinetic energy force component (F_k) may be directly proportional to the square of the rotational speed that fastener **60** is being driven at. As rotational speed of fastener **60** increases, the torque force component (F_t) needed to drive fastener **60** into structure **76** may be reduced. More specifically, fastener **60** may be driven at a rotational speed that reduces the torque force component (F_t) required to drive fastener **60** into structure **76** below the torsional strength of fastener **60**. As such, fastener **60** may cut threads into structure **76**, even where structure **76** has a torsional resistance that is greater than the torsional strength of fastener **60**.

[0026] However, once fastener **60** is fully inserted into structure **76** and head **66** abuts structure **76**, the force (F_i) required to further insert fastener **60** into structure **76** may be increased by the force of friction (F_{f2}) from head **66** on structure **76**. In order to maintain rotation of fastener **60**, force (F_s) must be increased. If the rotational speed that fastener **60** is being driven at remains constant, the torque force component (F_t) increases. Once the torque force component (F_t) exceeds the torsional strength of breakaway region **74**, breakaway portion **62** may be separated from fastening portion **64**. Alternatively, some other torque limiting feature of fastener **60** or the driving assembly may prevent further transmission of driving torque to fastening portion **64**.

[0027] However, the force (F_s) applied to drive fastener **60** may be limited such that it is greater than the sum of the force (F_c) needed to cut (or tap) threads and the force of friction (F_{f1}) from the threads on structure **76**, but less than a strip-out force (F_{so}), ($F_{so}>F_s>F_c+F_{f1}$). Strip-out may occur when fastener **60** is located within structure **76** and rotationally driven without further insertion into structure **76**. In order to avoid a strip-out condition once fastener **60** is inserted into structure **76** and fastener head **66** is seated against structure **76**, the force applied to fastener **60** (F_s) may be limited such that it is less than the sum of the force (F_c) needed to cut (or tap) threads, the force of friction (F_{f1}) from the threads on structure **76**, and the force of friction (F_{f2}) from head **66** on structure **76**, which is less than the strip-out force (F_{so}), ($F_{so}>F_c+F_{f1}+F_{f2}>F_s$).

[0028] While discussed with regard to pilot hole **78**, the arrangement discussed above may also be used where fastener **60** is a self-drilling fastener and there is no pilot hole. In the self-drilling configuration, the discussion above applies equally, except the force (F_i) needed to drive fastener **60** may be increased by a drilling force (F_d). Accordingly, the kinetic energy force component (F_k) of fastener **60** may also be increased in order to keep the torque force component (F_t) below the torsional strength of fastener **60**.

[0029] Pilot hole **78** may have a diameter that is greater than the minor diameter and less than the major diameter of fastener **60**. The rotational speed needed to drive fastener **60** may vary based on the relation between the size of pilot hole **78**, the major diameter of fastener **60**, the length of threaded shank **72**, and the material density of structure **76** relative to the material density of fastener **60**.

[0030] More specifically, as the diameter of pilot hole **78** is increased, the rotational speed needed to drive fastener **60** is reduced and as the diameter of pilot hole **78** is decreased, the rotational speed needed to drive fastener **60** is increased. Similarly, as the length of threaded shank **72** is increased, the rotational speed needed to drive fastener **60** is increased and as the length of threaded shank **72** is decreased, the rotational speed needed to drive fastener **60** is decreased. As the material density of structure **76** is increased relative to the material density of fastener **60**, the rotational speed needed to drive fastener **60** is increased and as the material density of structure **76** is decreased relative to the material density of fastener **60**, the rotational speed needed to drive fastener **60** is decreased.

[0031] In operation, adapter assembly **14** may be coupled to powered driver **12** and a desired driving speed may be selected for powered driver **12**. Fastener **60** may be loaded into adapter assembly **14** and an end of fastener **60** may be placed against an opening of pilot hole **78** and fastener **60** may be axially aligned with pilot hole **78**. Fastener **60** may then be driven into pilot hole **78**, as discussed above.

[0032] More specifically, powered driver **12** may be rapidly actuated, rather than gradually actuated, to quickly generate a desired rotational speed. Downward force may be applied to fastener **60** by displacement of plunger **16** into engagement with fastener **60** once powered driver **12** has been actuated to achieve the desired rotational speed to drive fastener **60** into structure **76**. Fastener **60** may be formed from a material that has a greater or lesser torsional strength than the torsional resistance of structure **76**. However, even when fastener **60** is formed from a material having a lesser torsional strength than the torsional resistance of structure **76**, fastener **60** may still be driven into pilot hole **78** and may tap pilot hole **78** due to the kinetic energy force component (F_k) and the torque force component (F_t) of fastener **60**, as discussed above.

[0033] More specifically, when fastener **60** is driven into pilot hole **78** at a high rotational speed, the force (F_s) applied by fastener **60** may be great enough to tap structure **76**, such as bone. As indicated above, when the rotational speed of fastener **60** is great enough, the kinetic energy force component (F_k) may reduce the torque force component (F_t) needed to drive fastener **60** to a level below the torsional strength of fastener **60**. Since the entire fastener **60** (breakaway portion **62** and fastening portion **64**) is rotating at the high rotational speed, a minimal amount of torque is transmitted through fastener **60**, allowing fastener **60** to cut threads into structure **76** even when structure **76** has a torsional resistance that is greater than the torsional strength of fastener **60**.

[0034] As discussed above, once head **66** of fastener **60** bottoms out on an outer surface of structure **76**, an amount of torque required to drive fastener **60** further into structure **76** becomes too great for the kinetic energy force component (F_k) of fastener **60** and the torque force component (F_t) is increased. Torque may then be transmitted to breakaway region **74** causing breakaway portion **62** to separate from fastening portion **64**. Powered driver **12** may then be turned off and breakaway portion **62** may then be ejected from adapter assembly **14** through use of ejector shaft **24**.

[0035] Several parameters may be varied for driving fastener **60** in the method discussed above. For example, parameters that may be used for the appropriate fastener and driving arrangement according to the method described above may include the major and minor diameters of the threaded shank **72**, the body length of threaded shank **72**, the pilot hole diameter, the downward force applied to fastener **60**, the speed ramp up of powered driver **12**, the set speed of powered driver **12**, rate of trigger actuation of powered driver **12**, and the material properties of structure **76** and fastener **60**, such as material densities. More specifically, Table 1 below includes several configurations and associated parameter values for driving fastener **60** in the manner discussed above. The configurations listed below are examples and may generally apply to structure **76** being bone and fastener **60** being formed from a polymer. As indicated above, fastener **60** may be formed from a material that has a greater or lesser torsional strength than the torsional resistance of structure **76**. In the examples listed below, the polymer formed fastener **60** may have a torsional strength less than the torsional resistance of bone.

TABLE 1

major diameter (mm)	body length (mm)	pilot hole diameter (mm)	driver speed (rpm)
1.5	5	1.3	12,000
1.5	3	1.1	20,000
1.5	4	1.1	25,000-30,000
1.5	4	1.2	25,000-30,000
1.5	5	1.1	25,000-30,000
1.5	5	1.2	25,000-30,000
1.5	8	1.3	25,000-30,000

What is claimed is:

1. A method comprising:

rotating a threaded fastener at a first rotational speed, said rotating providing a kinetic energy force component for the fastener based on the first rotational speed;

driving the fastener into a structure based on said rotating, said structure providing a torsional resistance during said driving greater than a torsional strength of the fastener and said driving providing a torque force component applied to the fastener; and

cutting threads into the structure with the fastener based on said driving, said driving applying a total force to the structure from the fastener including the kinetic energy force component and the torque force component, wherein the total force applied by the fastener is greater than or equal to a force required for said cutting and the torque force component is less than the torsional strength of the fastener.

2. The method of claim **1**, wherein the structure includes bone.

3. The method of claim **2**, wherein the fastener is formed from one of a polymer, a metal, a biocompatible non-resorbable material, a biocompatible resorbable material, a ceramic, a composite material, an allograft and a xenograft.

4. The method of claim **1**, further comprising terminating said driving when a predetermined torque limit is applied to the fastener.

5. The method of claim **4**, wherein one of the fastener and the driver includes a torque limiting feature that produces said terminating when an engagement between the fastener and the structure provides a frictional force between the fastener and the structure resulting in a torque that is greater than the predetermined torque limit.

6. The method of claim **5**, wherein the frictional force includes an engagement between a head of the fastener and the structure.

7. The method of claim **1**, further comprising forming a pilot hole having a first diameter greater than a minor diameter of the fastener and less than a major diameter of the fastener, said driving including driving the fastener into the pilot hole.

8. The method of claim **7**, wherein a frictional force is applied to the threads of the fastener as the fastener is driven into the structure, the total force applied by the fastener being greater than the force required for said cutting and the frictional force.

9. The method of claim **1**, wherein said driving includes drilling a hole in the structure.

10. The method of claim **9**, wherein a drilling force is applied to the fastener as the fastener is driven into the structure, the total force applied by the fastener being greater than the force required for said cutting and said drilling.

11. The method of claim **1**, wherein the first rotational speed is at least 12,000 revolutions per minute.

12. A method comprising:

applying a kinetic energy force component to a fastener having a torsional strength by rotating the fastener at a first rotational speed;

applying a torque force component to the fastener;

driving the fastener into a structure based on the combination of the kinetic energy and torque force components, wherein the torsional resistance provided by the structure during said driving is greater than a torsional strength of the fastener and the torque force component is less than the torsional strength of the fastener during said driving; and

terminating said driving when the fastening portion is inserted a predetermined amount into the structure.

13. The method of claim **12**, wherein said terminating occurs when an additional torque force component is applied to the fastener based on a frictional engagement between a head of the fastener and the structure.

14. The method of claim **12**, wherein the structure includes bone.

15. The method of claim **14**, wherein the fastener is formed from one of a polymer, a metal, a biocompatible non-resorbable material, a biocompatible resorbable material, a ceramic, a composite material, an allograft and a xenograft.

16. The method of claim **12**, further comprising forming a pilot hole having a first diameter greater than a minor diameter of the fastener and less than a major diameter of the fastener, said driving including driving the fastener into the pilot hole.

17. The method of claim **16**, wherein a frictional force is applied to the threads of the fastener as the fastener is driven into the structure, the combination of the kinetic energy and torque force components of the fastener being greater than the force required for said cutting and the frictional force.

18. The method of claim **12**, wherein said driving includes drilling a hole in the structure.

19. The method of claim **18**, wherein a drilling force is applied to the fastener as the fastener is driven into the structure, the combination of the kinetic energy and torque force components of the fastener being greater than the force required for said cutting and said drilling.

20. The method of claim **12**, wherein the first rotational speed is at least 12,000 revolutions per minute.

21. An apparatus comprising:

a threaded fastener having a torsional strength; and

a driver engaged with and adapted to drive said fastener at a first rotational speed into a structure and apply a torque force component to said fastener, said fastener adapted to have a kinetic energy force component based on the first rotational speed and to apply a total force to the structure including the torque force component and the kinetic energy force component that cuts threads into the structure, wherein the total force is greater than or equal to a force required to cut the threads and the torque force component is less than the torsional strength of said fastener.

* * * * *