The abstract of the patent application describes a soft tissue attachment system and clip. The clip is designed to secure to a bone plate or directly to a bone. It comprises a head having a shape suitable for allowing the passage of a suture during attachment of soft tissue to bone. One or more clips can be secured to a bone plate through a variety of means, including a snap configuration, a screw configuration, and a bendable prong configuration. The clip can be continuous with an adjacent clip, forming a multi-clip assembly that can either be secured to a bone plate or secured directly to a bone without a bone plate.
SOFT TISSUE ATTACHMENT SYSTEM AND CLIP

CROSS REFERENCES TO RELATED APPLICATIONS

[0001] This application claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 61/045860, filed on April 17, 2008, the complete disclosure of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to orthopedic devices used in the reattachment of soft tissue to bone in acute injuries or reconstructive procedures.

BACKGROUND OF THE INVENTION

[0003] The present device and method provides a significant improvement for soft tissue attachment or reattachment to bone in acute injury or in reconstructive procedures. The various embodiments of the present invention can be used in conjunction with bone plates or by itself.

[0004] Musculoskeletal injuries constitute combinations of bone and soft tissue injury. As such, bone fractures frequently have associated tendon or ligament tears. Fractures around joints - known in the art as periarticular fractures - are classic examples of combined bone and tendon, or bone and ligament injuries. Existing plate systems utilized in orthopaedic surgical procedures, such as fracture fixation or reconstruction procedures, provide limited options for incorporating additional soft tissue anchoring into the plate. In most instances the plates designed for use in periarticular fracture procedures will have a few small orifices for the passage of a curved surgical needle. A torn or avulsed tendon can be reattached to the bone at the time of fracture fixation through the small orifices on the plates. Often, the small amount and small size of the orifices on the plate are not sufficient to repair significant soft tissue components. In addition, it is often very difficult to pass a needle, curved or straight, through these orifices once the plate
has been screwed to the bone. Accordingly, existing bone plates provide limited options for soft tissue reattachment.

[0005] While the clinical success of bone anchors for the reattachment of tendon or ligament in musculoskeletal reconstruction is well documented, most existing bone anchors fail where the bone is very soft - as, or example, in severe osteopenia - or where the bone is very fragmented - as, for example, in fractures with severe bone fragmentation or comminution. In these instances, traditional bone anchors are inadequate for the reattachment of tendons and ligaments to bone.

[0006] It is therefore an object of the present invention to broaden the usefulness of bone plates by introducing additional features to plate design and fabrication that facilitate the reattachment of soft tissue, tendons, and ligaments to bone. The present invention has applications in fracture situations, and reconstructive procedures alike.

[0007] It is a further object of the present invention to provide a means of soft tissue reattachment or attachment to bone that can be used by itself without a bone plate; specifically, when other traditional methods, such as bone anchors, will not provide sufficient strength for repair.

**SUMMARY OF THE INVENTION**

[0008] The present invention generally comprises a suture attachment clip having various embodiments which provide multiple options for soft tissue repair to a bone structure.

[0009] In one embodiment of the present invention, the suture attachment clip comprises a head suitably shaped to allow the passage of a suture during the attachment of soft tissue to bone. A plurality of individual clips can attach to a bone plate by snapping the respective clips into corresponding receiving orifices on the bone plate, preferably located on the side of the bone.
plate. The clips can be attached to the bone plate at the time of manufacture or at the time of surgery.

[0010] In another embodiment of the present invention, the plurality of individual clips are attached to the bone plate by screwing each respective clip into a corresponding receiving orifice on the bone plate, preferably located on the side of the bone plate and preferably threaded internally. The clips can be screwed into the bone plate at the time of manufacture or at the time of surgery.

[0011] In yet another embodiment of the present invention, the plurality of individual clips are attached to a bone plate by inserting a free end of each respective clip through a corresponding pair of receiving orifices in the bone plate, preferably located on the side of the bone plate. The free ends of the clip are then bent through a corresponding pair of exit orifices on the bone plate, wherein the clip is fixed in place. In this embodiment, a clip can be designed and manufactured specifically to fit an existing bone plate's orifices, or alternatively, the bone plate and clip can be simultaneously and compatibly designed and manufactured. Each clip has a head suitably shaped to allow the passage of a suture during the repair of soft tissue to bone. The clips can be attached to the bone plate at the time of manufacture or at the time of the actual surgery.

[0012] In yet another embodiment of the present invention, the terminal end of one suture attachment clip is continuous with the terminal end of an adjacent suture attachment clip, thus forming a single multi-clip assembly. Each clip of the multi-clip assembly has a head suitably shaped to allow the passage of a suture during the attachment of soft tissue to bone. The multi-clip assembly attaches to the bone plate by snapping the multi-clip assembly to corresponding receiving channels on the bone plate. The receiving channels are preferably located on the undersurface of the bone plate. To further secure the multi-clip assembly to the bone plate, the
multi-clip assembly could alternatively be fastened to the bone plate by locking screws or fasteners. Depending on the fastening method used, the multi-clip assembly can be attached to the bone plate at the time of manufacture or at the time of the actual surgery.

[0013] The multi-clip assembly can also be used without attachment to a bone plate. In this embodiment of the present invention, the multi-clip assembly is fastened to the bone with standard bone screws or fasteners through a plurality of eyelets positioned at various points on the multi-clip assembly.

**DESCRIPTION OF THE DRAWINGS**

[0014] FIG. 1 illustrates a top perspective view of an individual clip with a snap configuration.

[0015] FIG. 2 illustrates a plurality of individual clips with snap configurations attached to a bone plate.

[0016] FIG. 3 illustrates a top perspective view of an individual clip with a threaded screw configuration.

[0017] FIG. 4 illustrates a plurality of individual clips with threaded screw configurations attached to a bone plate.

[0018] FIG. 5 illustrates a top perspective view of an individual clip with a dual prong configuration.

[0019] FIG. 6 illustrates a plurality of individual clips with bendable prong configurations attached to a bone plate.

[0020] FIG. 7 illustrates a top perspective view of a multi-clip assembly.

[0021] FIG. 8 illustrates a top perspective view of a bone plate with the multi-clip assembly attached to the underside of the bone plate.
FIG. 9 illustrates a bottom view of a bone plate with a receiving channel for the multi-clip assembly.

FIG. 10 illustrates a perspective view of the multi-clip assembly with eyelets and bone screws for attachment without a bone plate.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in FIG. 1, in one embodiment of the present invention, the suture attachment clip 1 comprises a head 2 suitably shaped to allow the passage of a suture during the attachment of soft tissue to bone. In this embodiment, the head 2 preferably has a first and second lobe 3 and 4. In a preferred embodiment of the present invention, the first and second lobes 3 and 4 are symmetrical with respect to one another. In a preferred embodiment of the present invention, first and second lobes 3 and 4 are continuous with first and second prongs 5 and 6 wherein first prong 5 has a first outwardly protruding terminal end 7 and second prong 6 has a second outwardly protruding terminal end 8. Preferably, the head 2, prongs 5 and 6, and terminal ends 7 and 8 form an inverse-omega shape when clip 1 is viewed from the top perspective depicted in FIG. 1.

As shown in FIG. 2, a plurality of individual clips 1 can attach to a bone plate 9 by snapping prongs 5 and 6 of each respective clip 1 into a corresponding receiving orifice 10 on the bone plate 9. The receiving orifice 10 is preferably located on the edge of the bone plate 9. In this snapping configuration, pressure is applied to the prongs 5 and 6 so that the prongs are squeezed toward one another until each terminal end 7 and 8 can pass through the receiving orifice 10. When terminal ends 7 and 8 have sufficiently passed through the receiving orifice 10, pressure on the prongs 5 and 6 is released so that the prongs contact the edges of the receiving orifice 10.
orifice 10, thereby securing the clip 1 to the bone plate 9. On or more clips 1 can be attached to
the bone plate at the time of manufacture or at the time of surgery.

[0026] As shown in FIG. 3, in another embodiment of the present invention, the suture
attachment clip 1 comprises a head 2 suitably shaped to allow the passage of a suture during the
attachment of soft tissue to bone. In this embodiment, the head 2 preferably has a first and
second lobe 3 and 4 which fuse into a single prong 11. In a preferred embodiment of the present
invention, the first and second lobes 3 and 4 are symmetrical with respect to one another. In a
preferred embodiment of the present invention, single prong 11 has external threading 12.

[0027] As shown in FIG. 4, in the threaded screw configuration of the present invention, a
plurality of individual clips 1 are attached to a bone plate 9 by screwing the single prong 11 of
each respective clip 1 into a corresponding receiving orifice 13 on the bone plate 9, thereby
securing the clip 1 to the bone plate 9. The receiving orifice 13 is preferably located on the edge
of the bone plate 9 and is preferably threaded internally. On or more clips 1 can be screwed into
the bone plate at the time of manufacture or at the time of surgery.

[0028] As shown in FIG. 5, in another embodiment of the present invention, the suture
attachment clip 1 comprises a head 2 suitably shaped to allow the passage of a suture during the
attachment of soft tissue to bone. In this embodiment, the head 2 preferably has a first and
second lobe 3 and 4. In a preferred embodiment of the present invention, the first and second
lobes 3 and 4 are symmetrical with respect to one another. In a preferred embodiment of the
present invention, first and second lobes 3 and 4 are continuous with first and second bendable
prongs 14 and 15. In a preferred embodiment of the present invention, the first bendable prong
14 is parallel to the second parallel prong 15. In a preferred embodiment of the present
invention, first bendable prong 14 is continuous with first terminating end 16, and second bendable prongs 15 is continuous with second terminating end 17.

[0029] As shown in FIG. 6, in the bendable prong configuration of the present invention, a plurality of individual clips 1 are attached to a bone plate 9 by inserting bendable prongs 14 and 15 of each respective clip 1 through corresponding first and second receiving orifices 18 and 19 in the bone plate. Receiving orifices 18 and 19 are preferably located on the edge of bone plate 9. In this embodiment, bendable prongs 14 and 15 are bent through corresponding first and second exit orifices 20 and 21 on the bone plate 9. Exit orifices 20 and 21 are preferably located on the edge of bone plate 9. As shown in FIG. 6, when bendable prongs 14 and 15 are bent through exit orifices 20 and 21, first and second terminating ends 16 and 17 face away from the bone plate 9 and toward the head 2 of the clip 1, thus securing the clip 1 to the bone plate 5. In this embodiment, clip 1 can be designed and manufactured specifically to fit an existing bone plate's orifices, or alternatively, the bone plate and one or more clips can be simultaneously and compatibly designed and manufactured. One or more clips 1 can be attached to the bone plate at the time of manufacture or at the time of the actual surgery.

[0030] As shown in FIG. 7, in yet another embodiment of the present invention, at least one terminal end of each clip 1, as depicted in FIG. 1, is continuous with the terminal end of an adjacent clip. The process can be repeated to form a plurality of linked clips, or a multi-clip assembly 22. Each clip 1 has a head suitably shaped to allow the passage of a suture during the attachment of soft tissue to bone. As shown in FIGS. 8 and 9, the multi-clip assembly 22 can preferably attach to the bone plate 9 by snapping the multi-clip assembly to corresponding receiving channels 23 on the bone plate 9. The receiving channels 23 are preferably located on the undersurface of the bone plate 9. While any portion of the multi-clip assembly can interlock
with the corresponding receiving channels 23, as shown in FIG. 8, in a preferred embodiment of the present invention, a portion of the head 2 of each clip 1 linked together in the multi-clip assembly 22 should remain sufficiently exposed beyond the edge of the bone plate 9 in order to allow for the passage of a suture.

[0031] To further secure the multi-clip assembly 22 to the bone plate 9, the multi-clip assembly could alternatively be fastened to the bone plate by locking screws or fasteners. Depending on the fastening method used, the multi-clip assembly can be attached to the bone plate at the time of manufacture or at the time of the actual surgery.

[0032] As shown in FIG. 10, the multi-clip assembly 22 can also be used without a bone plate. In this embodiment of the present invention, the multi-clip assembly 22 is fastened to the bone by inserting standard bone screws 23 or fasteners through a plurality of eyelets 24 positioned at various points on the multi-clip assembly 22, preferably at the juncture of the respective terminal ends of each linked individual clip 1 within the multi-clip assembly 22.
CLAIMS

1. A suture attachment clip comprising a head suitably shaped to allow the passage of a
suture during the attachment of soft tissue to bone.

2. The suture attachment clip of claim 1 wherein said head further comprises a first and
second lobe, wherein said first lobe is continuous with a first prong having a first outwardly
protruding terminal end, and said second lobe is continuous with a second prong having a second
outwardly protruding terminal end.

3. The suture attachment clip of claim 2 wherein said clip is capable of attaching to a bone
plate by snapping said first prong and said second prong into a corresponding receiving orifice
on said bone plate.

4. The suture attachment clip of claim 2 wherein said second outwardly protruding terminal
end is continuous with a first outwardly protruding terminal end of a second said suture
attachment clip.

5. The suture attachment clip of claim 4 wherein said clip attaches to a bone plate by
snapping into a corresponding receiving channel on said bone plate.

6. The suture attachment clip of claim 4 further comprising an eyelet for inserting bone
screws or fasteners therethrough.

7. The suture attachment clip of claim 1 wherein said head further comprises a first and
second lobe, wherein said first and second lobes are continuous with a single prong.

8. The suture attachment clip of claim 7 wherein said clip is capable of attaching to a bone
plate by inserting said single prong into a corresponding receiving orifice on said bone plate.

9. The suture attachment clip of claim 7 wherein said single prong is externally threaded.
10. The suture attachment clip of claim 1 wherein said head further comprises a first and second lobe, said first lobe being continuous with a first bendable prong and said second lobe being continuous with a second bendable prong.

11. The suture attachment clip of claim 10 wherein said first and second bendable prongs are parallel to one another.

12. The suture attachment clip of claim 10 wherein said clip is capable of attaching to a bone plate by inserting said first and second bendable prongs through first and second receiving orifices in said bone plate; bending said first and second parallel prongs through first and second exit orifices on said bone plate.

13. A method for attaching soft tissue to bone comprising the steps of providing a clip having a head suitably shaped to allow the passage of a suture; and passing a suture through said clip during the attachment of soft tissue to bone.

14. The method of claim 13 further comprising the step of passing said suture through a first or second lobe on said head, said first lobe being continuous with a first prong having a first outwardly protruding terminal end, and said second lobe being continuous with a second prong having a second outwardly protruding terminal end.

15. The method of claim 14 further comprising the step of snapping said first prong and said second prong into a corresponding receiving orifice on a bone plate.

16. The method of claim 14 wherein said second outwardly protruding terminal end is continuous with a first outwardly protruding terminal end of a second said suture attachment clip.

17. The method of claim 16 further comprising the step of attaching said clip to a bone plate by snapping said clip into a corresponding receiving channel on said bone plate.
18. The method of claim 16 further comprising the step of inserting bone screws or fasteners through an eyelet on said clip.

19. The method of claim 13 further comprising the step of passing said suture through a first or second lobe on said head, said first and second lobes being continuous with a single prong.

20. The method of claim 19 further comprising the step of attaching said clip to a bone plate by inserting said single prong into a corresponding receiving orifice on said bone plate.

21. The method of claim 19 wherein said single prong is externally threaded.

22. The method of claim 13 further comprising the step of passing said suture through a first or second lobe on said head, said first lobe being continuous with a first bendable prong and said second lobe being continuous with a second bendable prong.

23. The method of claim 22 wherein said first and second bendable prongs are parallel to one another.

24. The method of claim 22 further comprising the step of attaching said clip to a bone plate by inserting said first and second bendable prongs through first and second receiving orifices in said bone plate; bending said first and second parallel prongs through first and second exit orifices on said bone plate.
AMENDED CLAIMS
received by the International Bureau on
26 November 2008 (26.11.2008)

CLAIMS

1. A suture attachment clip comprising a head suitably shaped to allow the passage of a suture during the attachment of soft tissue to bone; said head further comprising one or more lobes, said lobes enclosing a space for the passage of a suture.

2. The suture attachment clip of claim 1 wherein said head farther comprises a first and second lobe, wherein an end of said first lobe extends to form a first prong so that said first prong is continuous with said first lobe, said first prong having a first outwardly protruding terminal end; and wherein an end of said second lobe extends to form a second prong so that said second prong is continuous with said second lobe, said second prong having a second outwardly protruding terminal end,

3. The suture attachment clip of claim 2 wherein said clip is capable of attaching to a bone plate by snapping said first prong and said second prong into a corresponding receiving orifice on said bone plate,

4. The suture attachment clip of claim 2 wherein said second outwardly protruding terminal end of a second suture attachment clip so that said second outwardly protruding terminal is continuous with said first outwardly protruding terminal end of said second said suture attachment clip,

5. The suture attachment clip of claim 4 wherein said clip attaches to a bone plate by snapping into a corresponding receiving channel on said bone plate.

6. The suture attachment clip of claim 4 further comprising an eyelet for inserting bone screws or fasteners therethrough.

7. The suture attachment clip of claim 1 wherein said head further comprises a first and second lobe, wherein said first and second lobes extend to form a single prong so that said first and second lobes are continuous with said single prong.

8. The suture attachment clip of claim 7 wherein said clip is capable of attaching to a bone plate by inserting said single prong into a corresponding receiving orifice on said bone plate,

9. The suture attachment clip of claim 7 wherein said single prong is externally threaded.

10. The suture attachment clip of claim 1 wherein said head further comprises a first and second lobe, wherein an end of said first lobe extends to form a

AMENDED SHEET (ARTICLE 19)
first bendable prong so that said first bendable prong is continuous with said first lobe, and wherein an end of said second lobe extends to form a second bendable prong so that said second bendable prong is continuous with said second lobe.

11. The suture attachment clip of claim 10 wherein said first and second bendable prongs are parallel to one another.

12. The suture attachment clip of claim 10 wherein said clip is capable of attaching to a bone plate by inserting said first and second bendable prongs through first and second receiving orifices in said bone plate, and bending said first and second parallel prongs through first and second exit orifices on said bone plate.

13. A method for attaching soft tissue to bone using a clip comprising a passage of a suture, said head having one or more lobes, said lobes enclosing a space for the passage of a suture; said method comprising the step of passing a suture through said enclosed space during the attachment of soft tissue to bone.

14. The method of claim 13 further comprising the step of passing a suture through a first or second lobe on said head, wherein an end of said first lobe extends to form a first prong so that said first prong having a first outwardly protruding terminal end; and wherein an end of said second lobe extends to form a second prong so that said second prong is continuous with said second lobe, said second prong having a second outwardly protruding terminal end.

15. The method of claim 14 further comprising the step of snapping said first prong and said second prong into a corresponding receiving orifice on a bone plate.

16. The method of claim 14 wherein said second outwardly protruding terminal end extends to form a first outwardly protruding terminal end of a second suture attachment clip so that said second outwardly protruding terminal end of a second suture attachment clip is continuous with said first outwardly protruding terminal end.

17. The method of claim 16 further comprising the step of attaching said clip to a bone plate by snapping said clip into a corresponding receiving channel on said bone plate.

18. The method of claim 15 further comprising the step of inserting bone screws or fasteners through an eyelet on said clip.
19. The method of clair further comprising the step of passing a suture through a first or second lobe on said head, wherein said first and second lobes extend to form a single form so that said first and second lobes are continuous with said single prong.

20. The method of clair further comprising the step of attaching said clip to a bone plate by inserting said single prong into a corresponding receiving orifice on a bone plate.

21. The method of clair wherein said single prong is externally threaded.

22. The method of clair further comprising the step of passing a suture through a first or second lobe on said head, wherein an end of said first lobe extends to form a first bendable prong so that said first bendable prong is continuous with said first lobe, and wherein an end of said second lobe extends to form a second bendable prong so that said second bendable prong is continuous with said second lobe.

23. The method of clair wherein said first and second bendable prongs are parallel to one another.

24. The method of clair further comprising the step of attaching said clip to a bone plate by inserting said first and second bendable prongs through first and second receiving orifices on a bone plate, and bending said first and second parallel prongs through first and second exit orifices on a bone plate.
INTERNATIONAL SEARCH REPORT

International application No
PCT/US 08/63748

A CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/84 (2008.04)
USPC - 606/300
According to International Patent Classification (IPC) or to both national classification and IPC

B FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B17/84 (2008.04)
USPC - 606/300

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
A61B17/68, 17/56, 606/75, 139, 252

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST(USPT,PGPB,EPAB,JPAB), Google Scholar,
Search Terms Used suture clip, suture attachment clip, prong, snp, bone plate, suture anchor, removable/detachable suture attach$/secure/$fix/S, eye bolt

C DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No</th>
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<tbody>
<tr>
<td>X</td>
<td>US 6,149,653 A to (DESLAURIERS) 21 November 2000 (21 11 2000) Entire document especially, col 3, in 3-4, col 6, in 5-8, col 19, in 4-6 and FIGS 4a &amp; 39</td>
<td>1, 7-9, 13 &amp;19-21</td>
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D Further documents are listed in the continuation of Box C

* Special categories of cited documents
  `A` document defining the general state of the art which is not considered to be of particular relevance
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19 September 2008 (19 09 2008)

Date of mailing of the international search report
26 SEP 2008

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Form PCT/ISA/2 10 (second sheet) (April 2007)