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(54) Title: ADJUSTABLE TRIAL FEMORAL NECK ASSEMBLY

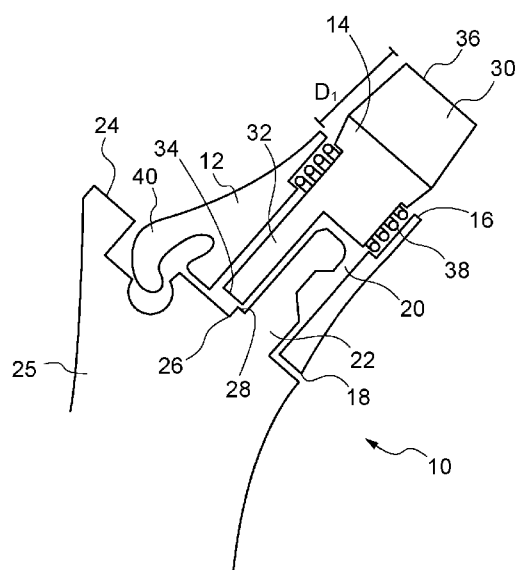


Fig. 1

(57) Abstract: The invention provides a kit in which progressive neck length is accommodated within the broach (25). This is achieved by the provision of a femoral neck length setting projection (26) on each size of broach that allows the neck length to be varied on the broach side of a broach/trial femoral neck assembly. This prevents the need for a different trial femoral neck component for each broach size. The inventory of trial femoral neck components within the instrument tray may therefore be reduced to one trial standard offset femoral neck component and/or one trial high offset femoral neck component.

ADJUSTABLE TRIAL FEMORAL NECK ASSEMBLY

FIELD OF THE INVENTION

The present invention relates generally to the field of orthopedics, and more particularly to trial femoral neck assemblies, kits and methods for use in intraoperative trialling of hip prostheses to determine an appropriate length for the definitive femoral neck component of a prosthetic hip joint.

BACKGROUND TO THE INVENTION

Optimal hip mechanics in hip arthroplasty is achieved through the selection of an appropriate neck length and head offset in the femoral component of the prosthetic hip implant.

The distance between the femoral stem component and the femoral head component, provided by the length of the neck of the femoral component, establishes the requisite head offset and neck length which in turn contributes to the desired range of motion, leg length, and tension in the soft tissue at the implant site. In order to optimize hip mechanics, it is desirable to select the leg length with precision. Femoral offset is an important clinical requirement. When offset is not restored, medialization of the femur can occur which results in impingement and possible instability. Additionally, if offset is not restored at the time of surgery, laxity of tissues can occur resulting in weakness and possible dislocation.

Conventionally, femoral stem components are offered in standard offset and high offset configurations to provide proper joint tension without affecting leg length or surgical technique.

Traditional implant stem geometry with a progressive neck length requires a different neck trial for each stem size and each offset variation. Trial femoral neck components are usually designed to work with the corresponding size of broach. This requires a large inventory of trial neck components within an instrument tray. In order to

reduce the inventory, it would be desirable to reduce the number of trial femoral neck components required.

Advantageously, the instrument tray would include a set of broaches of varying sizes, one trial standard offset trial femoral neck assembly and one trial high offset femoral neck assembly.

SUMMARY OF THE INVENTION

The invention provides a kit in which progressive neck length is accommodated within the broach. This is achieved by the provision of a femoral neck length setting projection on each size of broach that allows the neck length to be varied on the broach side of a broach/trial femoral neck assembly. This prevents the need for a different trial femoral neck component for each broach size. The inventory of trial femoral neck components within the instrument tray may therefore be reduced to one trial standard offset femoral neck component and/or one trial high offset femoral neck component.

Therefore, according to an aspect of the invention there is provided an adjustable trial femoral neck assembly comprising:

a broach attachment part comprising:

a proximally facing surface,
a broach facing surface, and
a bore extending inwardly from the broach facing surface and being dimensioned for receipt of a connecting element extending from a proximal surface of a broach by which the broach is connected to the broach attachment part,

wherein the assembly further comprises:

a femoral head attachment part comprising:

a proximal portion configured for removable attachment to a trial femoral head, and

a distal portion comprising a neck,

such that when the broach attachment part of the trial femoral neck assembly is connected to the broach, the connecting element is received within the bore, and a distal end of the neck engages with a proximal most surface of a femoral neck length setting projection that

projects beyond the proximal surface of the broach to thereby set the distance between the proximal facing surface of the broach attachment part and a proximal end of the proximal portion of the femoral head attachment part.

- 5 Optionally, the femoral neck length setting projection is defined by a step portion extending from a wall of the connecting element.

10 In some constructions, the femoral head attachment part is spring loaded such that the assembly is always in the smallest, most retracted position. This ensures that the spring is not under compression during trial reduction. Accordingly, the broach attachment part of the trial femoral neck assembly comprises a biasing means to bias the femoral head attachment part towards the broach attachment part. The biasing means may be a helical spring or a compression spring.

- 15 Optionally the trial femoral neck assembly is provided a standard offset femoral neck trial assembly or a high offset femoral neck trial assembly.

20 In some constructions, the trial femoral neck assembly is provided with a retaining feature that retains the neck assembly on the broach during trialling. This prevents disassociation of the neck from the broach. This retaining feature also prevents any inadvertent rotation of the neck assembly relative to the broach. An example of a suitable retaining feature is a live spring.

25 According to a second aspect of the invention, there is provided a kit for use in trialling of a femoral head, said kit comprising a trial femoral neck assembly as herein described, and further comprising:

30 a first broach having a femoral neck length setting projection with a proximal most surface that projects beyond the proximal surface of the broach by a first distance such that when the distal end of the neck engages with the proximal most surface of the femoral neck length setting projection the neck length of the adjustable trial femoral neck assembly is set at a first distance, and

a second broach having a femoral neck length setting projection with a proximal most surface that projects beyond the proximal surface of the broach by a second distance such that when the distal end of the neck engages with the proximal most surface of the femoral neck length setting projection the neck length of the adjustable trial femoral neck assembly is set at a second distance.

In some constructions, the second broach is larger than the first broach and wherein the proximal most surface of the femoral neck length setting projection on the second broach projects further beyond the proximal surface of the broach than the proximal most surface of the femoral neck length setting projection on the first broach, such that when the trial femoral neck assembly is assembled onto the second broach the trial femoral neck assembly has a longer neck length.

The kit includes at least one of a standard offset femoral neck trial assembly or a high offset femoral neck trial assembly.

According to a third aspect of the invention there is provided a method of selecting a femoral neck component for use in an orthopaedic joint prosthesis, the method comprising the steps of

- 20 (i) using a kit comprising:
 - an adjustable trial femoral neck assembly comprising:
 - a broach attachment part comprising:
 - a proximally facing surface,
 - a broach facing surface, and
 - 25 a bore dimensioned for receipt of a connecting element
- extending from a proximal surface of a broach by which the broach is connected to the broach attachment part, wherein the assembly further comprises:
 - a femoral head attachment part comprising:
 - a proximal portion configured for removable
 - 30 attachment to a trial femoral head and
 - a distal portion comprising a neck,

such that when the broach attachment part of the trial femoral neck assembly is attached to the broach, the connecting element extending from the proximal surface of a broach is received within the bore, and a distal end of the neck engages with a proximal most surface of a femoral neck length setting projection that projects beyond the proximal surface of the
 5 broach to thereby set the distance between the proximal facing surface of the broach attachment part and a proximal end of the proximal portion of the femoral head attachment part,

a first broach having a femoral neck length setting projection with a proximal most surface that projects beyond the proximal surface of the broach by a first
 10 distance such that when the distal end of the neck engages with the proximal most surface of the femoral neck length setting projection the neck length of the adjustable trial femoral neck assembly is set at a first distance, and

a second broach having a femoral neck length setting projection with a proximal most surface that projects beyond the proximal surface of the broach by a second
 15 distance such that when the distal end of the engages with the proximal most surface of the femoral neck length setting projection the neck length of the adjustable trial femoral neck assembly is set at a second distance,

- (ii) broaching a patient's femur using at least one of the first broach or second broach,
- 20 (iii) retaining the broach with the patient's femur,
- (iv) connecting the trial femoral neck assembly to the first broach or the second broach,
- (v) connecting a trial femoral head component to the trial femoral neck assembly, and
- 25 (vi) performing a trial reduction.

In some examples of the method, the trial femoral neck assembly that is connected to the first broach or second broach is a standard offset femoral neck trial assembly or a high offset femoral neck trial assembly.

DETAILED DESCRIPTION OF THE INVENTION

The invention will now be described, by way of example only, with reference to the following drawings, in which:

5 Figure 1 shows a schematic of a trial femoral neck assembly according to the invention.

 A schematic of an exemplary adjustable trial femoral neck assembly 10 is shown in Figure 1. The trial femoral neck assembly includes a broach attachment part 12 and a
10 femoral head attachment part 14.

 The broach attachment part 12 includes a proximally facing surface 16, a broach facing surface 18, and a bore 20 that extends inwardly from the broach facing surface 18.

15 The bore 20 is dimensioned for receipt of a connecting element 22 extending from a proximal surface 24 of a broach 25. The broach is connected to the broach attachment part 12 of the assembly via this connecting element.

 In the construction shown, the femoral neck length setting projection 26, provided
20 on the proximal surface of the broach, is defined by a stepped portion which is integral with, and extends in a medial direction from the connecting element 22. It is however envisaged that the femoral neck length setting projection 26 may be provided as a discrete element that is separate from the connecting element 22. For example, the femoral neck length setting projection 26 may be provided as a post that is spaced apart medially from
25 the connecting element 22.

 The femoral neck length setting projection 26 includes a proximal most surface 28 onto which at least a portion of the distal end 34 of the femoral head attachment portion will be engage.

30

The femoral head attachment part 14 includes a proximal portion 30 configured for removable attachment to a trial femoral head, and a distal portion comprising a neck 32.

When the broach attachment portion 12 is assembled onto a broach 25, a least a
5 portion of the distal end 34 of the neck 32 will engage at least a portion of the proximal most surface 28 of the femoral neck length setting projection 26. As shown in FIG. 1, a corner of the distal end 34 of the neck 32 will seat on the proximal most surface 28 of the connecting element 22.

Broaches are used during hip arthroplasty to replicate the definitive femoral stem.
10 Each incremental size of broach that is used in conjunction with the inventive trial femoral neck assembly as herein described includes a femoral neck length setting projection 26 that projects a different extent beyond the proximal surface 24 of the broach 25. With each increasing size of broach, the femoral neck length setting projection 26 extends a greater extent beyond the proximal surface of the broach 24. This results in an increase in neck
15 length with increasing sizes of broach because with each incremental size of broach the neck 32 of the femoral head attachment 14 part will not sit as deep within the broach attachment part 12. Engagement between the distal end 34 of the neck 32 and the proximal most surface 28 of the femoral neck length setting projection 26 will occur in a more proximal position. Accordingly, with each incrementally larger size of broach, the femoral
20 neck trial will have a longer neck length because the proximal portion 36 of the femoral head attachment part will be forced to sit more proud of the proximal facing surface of the broach attachment part 16. That is, the distance d_1 represented in FIG.1 will increase.

In the construction shown, a spring 38 connects the broach attachment portion 12 and the femoral head attachment part 14. The spring biases the femoral head attachment
25 part 14 towards the broach attachment portion 12. This ensures that the trial femoral neck assembly is always in the smallest, most retracted position, thereby ensuring that the spring is not under compression during trial reduction.

In the construction shown, the trial femoral neck assembly is provided with a
30 retaining feature 40 that retains the neck assembly on the broach during trialling. This prevents disassociation of the neck from the broach. This retaining feature also prevents

any inadvertent rotation of the neck assembly relative to the broach. An example of a suitable retaining feature is a live spring.

It will be appreciated by those skilled in the art that changes could be made to the
5 embodiments described above without departing from the broad inventive concept thereof.
It is understood, therefore, that this disclosure is not limited to the particular embodiments
disclosed, but it is intended to cover modifications within the spirit and scope of the
present disclosure as defined by the claims.

CLAIMS

1. An adjustable trial femoral neck assembly comprising:
 - a broach attachment part comprising:
 - 5 a proximally facing surface,
 - a broach facing surface, and
 - a bore extending inwardly from broach facing surface and being dimensioned for receipt of a connecting element extending from a proximal surface of a broach by which the broach is connected to the broach attachment part,
 - 10 wherein the assembly further comprises:
 - a femoral head attachment part comprising:
 - a proximal portion configured for removable attachment to a trial femoral head and
 - a distal portion comprising a neck,
 - 15 such that when the broach attachment part of the trial femoral neck assembly is attached to the broach, the connecting element extending from the proximal surface of a broach is received within the bore, and a distal end of the neck engages with a proximal most surface of a femoral neck length setting projection that projects beyond the proximal surface of the broach to thereby set the distance between the
 - 20 proximal facing surface of the broach attachment part and a proximal end of the proximal portion of the femoral head attachment part.
2. The adjustable trial femoral neck assembly according to claim 1, wherein the
25 femoral neck length setting projection is defined by a step extending from a wall of the connecting element.
3. The adjustable trial femoral neck assembly according to claim 1 or 2, wherein the
broach attachment part comprises a biasing means to bias the femoral head attachment part towards the broach attachment part.
- 30 4. The adjustable trial femoral neck assembly according to claim 3, wherein the biasing means is a helical spring.

5. The adjustable trial femoral neck assembly of any of claims 1 to 4, wherein the trial femoral neck assembly is a standard offset trial femoral neck assembly or a high offset trial femoral neck assembly.
- 5 6. A kit for use in trialing a femoral head, said kit comprising:
- a trial femoral neck assembly according to any of claims 1 to 5,
- a first broach having a femoral neck length setting projection with a proximal most surface that projects beyond the proximal surface of the broach by a first distance such that when the distal end of the neck engages with the proximal most surface of the femoral neck length setting projection the neck length of the adjustable trial femoral neck assembly is set at a first distance, and
- 10 a second broach having a femoral neck length setting projection with a proximal most surface that projects beyond the proximal surface of the broach by a second distance such that when the distal end of the neck engages with the proximal most surface of the femoral neck length setting projection the neck length of the adjustable trial femoral neck assembly is set at a second distance.
- 15 7. The kit according to claim 7, wherein the second broach is larger than the first broach and wherein the proximal most surface of the femoral neck length setting projection on the second broach projects further beyond the proximal surface of the broach than the proximal most surface of the femoral neck length setting projection on the first broach, such that when the trial femoral neck assembly is assembled onto the second broach the trial femoral neck assembly has a longer neck length.
- 20 8. The kit according to claim 6 or 7, wherein the kit includes a standard offset trial femoral neck assembly or a high offset trial femoral neck assembly.
- 25 9. A method of selecting a femoral neck component for use in an orthopaedic joint prosthesis, the method comprising the steps of:
- 30 (i) using a kit comprising:
- an adjustable trial femoral neck assembly comprising:
- a broach attachment part comprising:

a proximally facing surface,
a broach facing surface, and
a bore extending inwardly from the broach facing
surface and dimensioned for receipt of a connecting element extending from a
proximal surface of a broach by which the broach is connected to the broach
attachment part,

wherein the assembly further comprises:

a femoral head attachment part comprising:

a proximal portion configured for removable
attachment to a trial femoral head and

a distal portion comprising a neck,
such that when the broach attachment part of the trial femoral neck assembly is
attached to the broach, the connecting element extending from the proximal surface
of the broach is received within the bore, and a distal end of the neck engages with
a proximal most surface of a femoral neck length setting projection to thereby set
the distance between the proximal facing surface of the broach attachment part and
a proximal end of the proximal portion of the femoral head attachment part,

a first broach having a femoral neck length setting projection
with a proximal most surface that projects beyond the proximal surface of the
broach by a first distance such that when the distal end of the neck engages with the
proximal most surface of the femoral neck length setting projection the neck length
of the adjustable trial femoral neck assembly is set at a first distance, and

a second broach having a femoral neck length setting projection
with a proximal most surface that projects beyond the proximal surface of the
broach by a second distance such that when the distal end of the neck engages with
the proximal most surface of the femoral neck length setting projection the neck
length of the adjustable trial femoral neck assembly is set at a second distance,

(ii) broaching a patient's femur using at least one of the first broach or second
broach,

(iii) retaining the broach with the patient's femur,

(iv) connecting the trial femoral neck assembly to the first broach or the second
broach,

- (v) connecting a trial femoral head component to the trial femoral neck assembly, and
 - (vi) performing a trial reduction.
- 5 10. The method according to claim 9, wherein the trial femoral neck assembly connected to the first broach or the second broach is a standard offset trial femoral neck assembly or a high offset trial femoral neck assembly.

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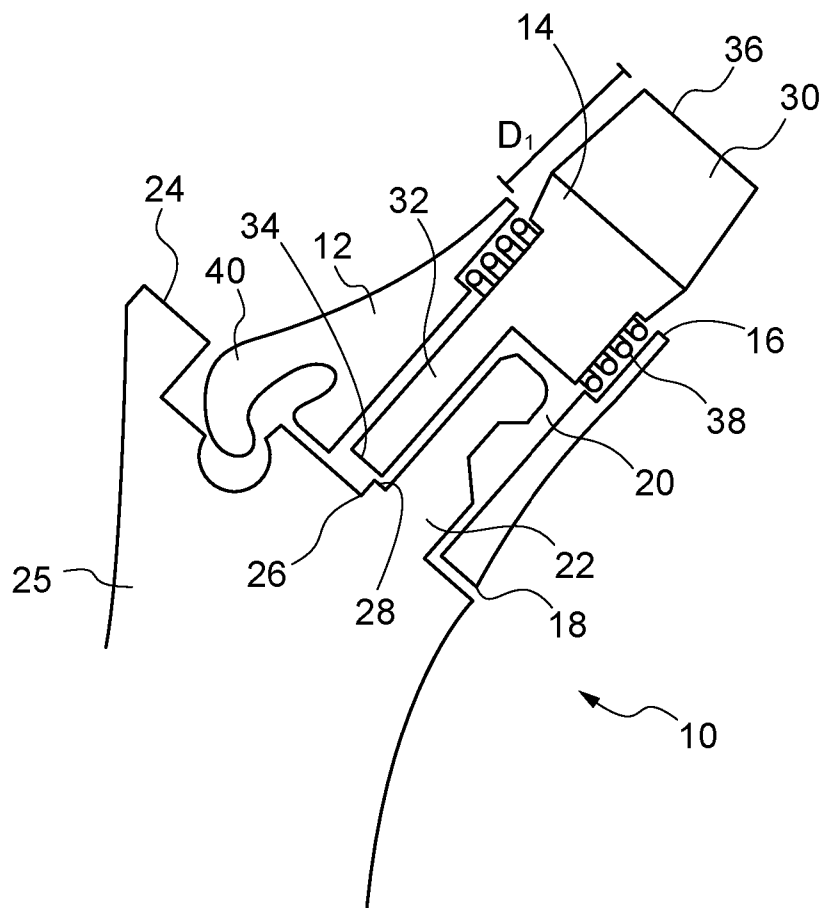


Fig. 1

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2020/053890

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/46 A61B17/16
ADD.

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)
A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/267372 A1 (VANASSE THOMAS M [US] ET AL) 30 December 2004 (2004-12-30) paragraph [0026] - paragraph [0030] paragraph [0038] - paragraph [0039] figures 1-4	1-3,5
X	US 4 963 155 A (LAZZERI MARK A [US] ET AL) 16 October 1990 (1990-10-16) abstract column 7, line 3 - line 17 figures 1,5	1,2,5
A	WO 2019/038026 A1 (DEPUY IRELAND ULTD CO [IE]) 28 February 2019 (2019-02-28) page 13, line 9 - line 32 figures 3a,3b	1,6
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Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

13 May 2020

Date of mailing of the international search report

27/05/2020

Name and mailing address of the ISA/

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Storer, John

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2020/053890

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 7 608 112 B1 (KUCZYNSKI JOHN D [US] ET AL) 27 October 2009 (2009-10-27) abstract figure 3 -----	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2020/053890

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 9, 10
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery.
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2020/053890

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004267372	A1	30-12-2004	NONE
US 4963155	A	16-10-1990	CA 2021148 A1 01-03-1991 US 4963155 A 16-10-1990
WO 2019038026	A1	28-02-2019	CN 110996857 A 10-04-2020 WO 2019038026 A1 28-02-2019
US 7608112	B1	27-10-2009	NONE