EXACTECH | **HIP**

Design Rationale

ALTEON®

HA FEMORAL STEM

Exactech® *Surgeon focused. Patient driven.™*

ALTEON®

Table of Contents

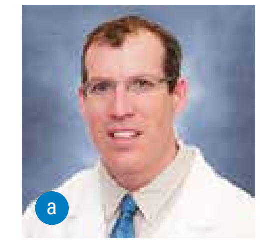
DESIGN TEAM 1
INTRODUCTION 2
DESIGN HISTORY 3
CLINICAL SUCCESS OF THE HA STEM 4
UNMET CLINICAL NEEDS
- Fixed Neck Lengths 5
- Distal Potting 5

DESIGN GOALS 6
IMPLANT DESIGN FEATURES
- Incremental Neck Sizing 8
- Incremental Stem Sizing 9
- Shorter Overall Stem Length 10
- HA Coating 11

INSTRUMENT DESIGN FEATURES
- Platform Instrumentation 12
- Broach Design 12

CONCLUSION 12
REFERENCES 13

Design Team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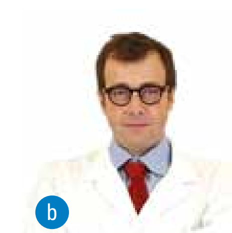
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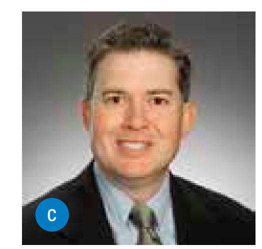
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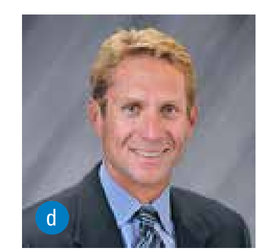
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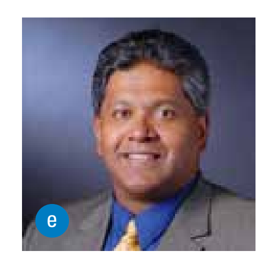
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The word "Alteon" is derived from the Latin word "altus" meaning "high," denoting Exactech's high performance, next-generation hip system. This system is designed to deliver a reproducible, efficient and predictable clinical experience.

Introduction

The Alteon® HA is a next-generation, fully hydroxyapatite-coated, tri-taper stem. It incorporates specific philosophies and is designed to improve surgical experiences and clinical outcomes.

The HA stem offers both collared and collarless designs intended to achieve immediate axial and rotational stability in the femoral canal. This is accomplished through a proprietary combination of:

- Stem Geometry
- HA Coating
- Incremental Sizing
- Neck Geometry
- Stem Length

Design History

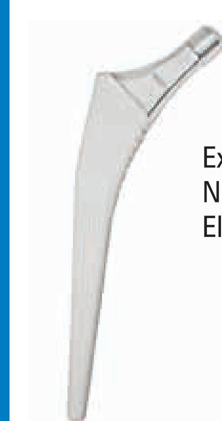
The Alteon HA is a primary hip femoral stem implant, historically categorized by the market as a fully hydroxyapatite (HA)-coated, tri-taper design. This design was based off the DePuy Corail stem of the 1980s which evolved from the cemented Müller stem of the 1970s. The clinical success of the Corail-style stem has been the foundation for several other competitive design iterations, including Exactech's Novation® Element Stem and the Alteon® HA Femoral Stem.

There are several growth drivers in total hip arthroplasty, and one of particular interest is the change in patient demographics seen specifically in the U.S. market. Over the past four decades the mean age for a total hip replacement patient has dropped to 67.6 years. This statistic is consistent with several data sources for total hip procedures.[2] Patients today are younger and more active than previous generations and value immediate post-operative recovery and pain management in order to quickly return to their activities of daily living.

At the same time, there is tremendous value placed on implant longevity from both the patient and surgeon communities. In addition to the patient demographics trending to a much younger age group, there are additional industry drivers that provide positive indication that the primary hip market segment will continue to grow including, but not limited to: continued and increased prevalence of the Direct Anterior Approach (DAA), emerging trends in outpatient total joint replacement, a desire for technique simplicity (broach-only techniques), and the introduction of next-generation prostheses.

Müller Cemented Stem

DePuy Corail



Exactech Novation Element

NEXT GENERATION

EXACTECH ALTEON HA FEMORAL STEM

Clinical Success of the HA Stem

Extensively HA-coated stems have been used clinically for more than 25 years and have shown excellent survivorship, as highlighted in the table below. Vidalain et al. noted "HA has proven highly efficient regarding bone ingrowth and bioactivity."[3]

Author	Year	# of Hips	Survivorship
Vidalain[3]	2011	347	97.7% at 15 years 96.8% at 18 years & 20 years 96.3% at 23 years
Hallan[4]	2007	5,456	98.9% at 7 years 98% at 10 years 97% at 15 years
Rokkum[5]	1999	94	98.9% at 8 years

CLINICAL HIGHLIGHTS

No cases of aseptic loosening of the femoral component.

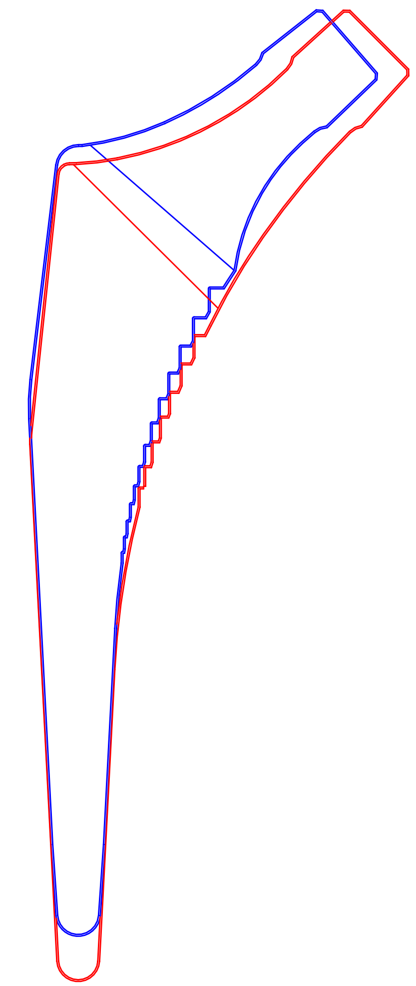
"Froimson et al (2007)[6] reported on 96 total hip arthroplasties prospectively followed in 86 patients. At a mean follow-up of 11.5 years, composite scores increased from a pre-operative mean of 5.5 (of 18) to 16.5 (of 18) at latest follow-up. Two patients required revision of both acetabular and femoral components, and the authors' report both of these stems were well fixed with considerable osteointegration."

Most successful prosthesis compared to 14 different stem designs.

"Hallan et al (2007)[4] reported on 11,516 total hip arthroplasties in 9,679 patients reported to the Norwegian arthroplasty register between 1987 and 2005. The fully HA coated stem was used in 5,456 hips. Mean follow-up for patients receiving the fully HA coated stem was 8.6 years. With stem revision for any reason as an endpoint, the authors report Kaplan-Meier estimated survivorships of 98.9 percent at seven years, 98 percent at 10 years, and 97 percent at 15 years."

No incidence of thigh pain.

"Reikerås and Gunderson (2003) reported on 291 total hip arthroplasties prospectively followed in 245 patients.[7] At a mean follow-up of 10 years, one patient had a stem revised due to post-traumatic mechanical failure. Hips with mechanical loosening of the acetabular component were excluded from clinical evaluation of hip function. Using the d'Aubigne and Postel scoring system, the authors report a mean post-operative pain score of six, a mean post-operative motion score of five, and a mean post-operative walking score of five. They found excellent results with a fully HA-coated femoral prostheses designed for press-fit insertion."



Unmet Clinical Needs

FIXED NECK LENGTHS

A study explored the effects of an extensively-coated HA stem prosthesis with fixed neck length design.[8] The average length of the remaining bone above the lesser trochanter after resection was 5.3mm±1.7mm with a range of 2-10mm.[8] Sixty-five percent of the patients (37/57) had lengthened the leg by 10-30mm. The 10-year survival rate of all femoral components was 100 percent.[8]

For the femoral stem to accurately reproduce the anatomy, it was concluded that an extensively-coated HA stem prosthesis with a fixed neck length requires an increase in the length of the femoral neck resection in order to achieve satisfactory long-term fixation and clinical outcomes.[8] The illustration to the left depicts the smallest sized Alteon HA stem (blue) in comparison to the previous generation's smallest stem size (red). The images were overlaid with the intention of maintaining the same leg length. Note the difference in resection levels between the two stems. The Alteon HA's proportional neck groupings are designed to minimize the need for a larger resection.

DISTAL POTTING

Another issue that can occur in total hip replacement is known as distal potting. This is what happens when an implant fills the femoral canal distally before proximal fixation can occur, which most often occurs in Dorr Type A Femora. When this occurs, the surgeon will have to utilize flexible reamers to clear the bone distally to allow for proper fixation to occur in the proximal region. The use of flexible reamers goes against the bone preserving methodology of the stem as cancellous bone is removed by use of the flexible reamers.

Design Goals

The Alteon HA Design Team set out to design a stem that accomplished the following:

1. The femoral stem shall achieve immediate axial and rotational stability.
2. The stem should be able to solve common kinematic issues without the need for modular neck components.
3. The stem should improve upon the sizing options as well as include collared and collarless options for both standard and extended offsets.
4. The stem should incorporate features that allow compatibility with all surgical approaches, but not compromise the ability of the geometric features to provide mechanical fixation.
5. The stem should have optimized HA properties.
6. The system should adopt the Alteon platform instrumentation.

Implant Design Features

The Alteon HA is a simple broach-only system that is reproducible and has been used in a variety of types (Dorr A, B, C) and sizes of femora.[9] The medial/lateral aspect has a six-degree taper that allows the stem to be capable of fixation in the metaphysis, diaphysis or both. The six-degree taper is designed to allow for a self-centering effect and a likelihood that more stems will be placed in neutral position.

The Alteon HA stem has mechanical-interlock features that are designed to provide initial mechanical stability which is needed for long term biologic fixation. These features are consistent with a design philosophy based on more than 25 years of clinical use.

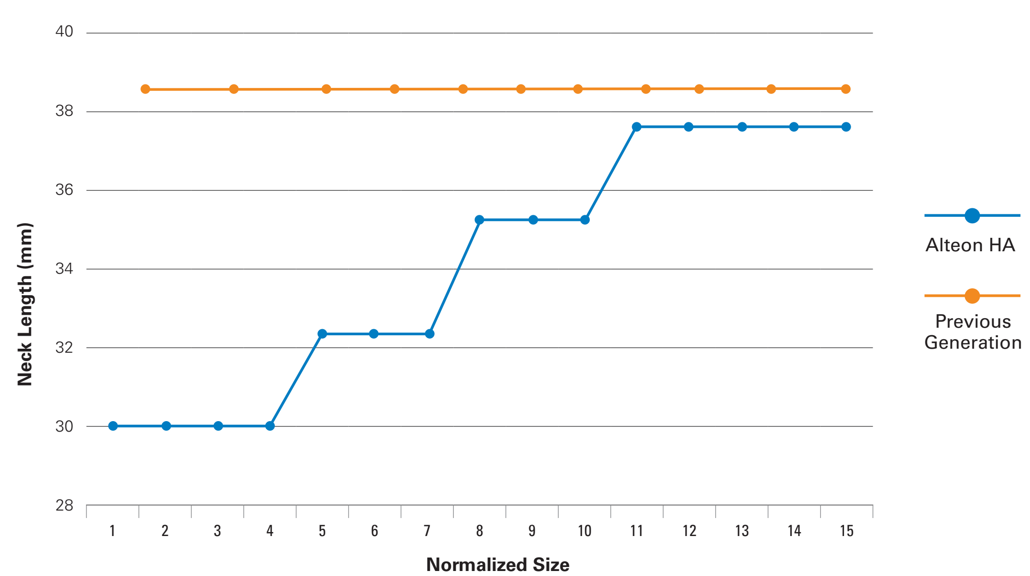
FEATURES INCLUDE:

- A **low-profile shoulder** that allows easy insertion in small incisions and is designed to help keep the stem out of varus alignment.
- **Horizontal proximal grooves** designed to convert hoop stress of the femur to compressive loads, which provide additional axial stability.
- **Distal vertical grooves** designed to facilitate rotational stability.
- **Progressive anterior-to-posterior tulip flare** and increased filling design of proximal zone designed to resist axial/torsional stresses, ensuring load transfer into the proximal femur to promote osseointegration.
- **Narrow anterior-to-posterior dimensions** for the medial/lateral design intended to conserve bone while providing torsional stability.
- **Trapezoidal cross-sections proximally and distally** designed to promote initial stability. Trapezoidal shape has been shown to have a more stable cross-section in the prepared femoral canal, encouraging a proximal load transfer of stresses.[10]
- **Six-degree taper** for the distal stem in the coronal plane.
- **Parallel-sided** with a taper along the proximal one-third of the stem in the sagittal projection.
- **Distal tip** design reduces stress concentration at the distal stem and bone interface, which has been shown to reduce the incidence of thigh pain.[10,11]

INCREMENTAL NECK SIZING

During the design process, consideration was given to the second design goal of solving common kinematic issues without the need for modular neck components. When solving unmet kinematic issues, careful consideration was taken when designing the neck grouping scheme for the Alteon HA stem. Some competitive designs feature base neck lengths that are too long, especially in the smaller sizes. Surgeons often found themselves cutting near the lesser trochanter or would have the potential of lengthening the patients' leg.[8] The average leg length discrepancy following total hip arthroplasty (THA) has been reported to be from 3mm to as high as 16mm.[12] The proportional neck lengths of the Alteon HA are designed to reduce the amount of neck resection needed while optimizing joint kinematics.

The Alteon HA stem has four base neck length groups to allow for an anatomic neck resection. The system was intentionally designed so that a change between the neck length groupings could be accommodated by changing the modular femoral head offset without affecting the overall total leg length. Additionally, the stem has two offsets, standard and extended, that share a 131-degree neck angle, to accomplish offset. A 131-degree neck angle has been shown to effectively reproduce femoral anatomy in most patients.[13,14,15] The direct lateral shift between the standard and extended offset makes it seamless to tighten the joint without changing leg length. The trapezoidal neck geometry allows for reduced material on the medial aspect to increase range of motion, demonstrated in bench testing to decrease the chance of post-operative dislocation, while material on the lateral side is maintained for strength.[17]



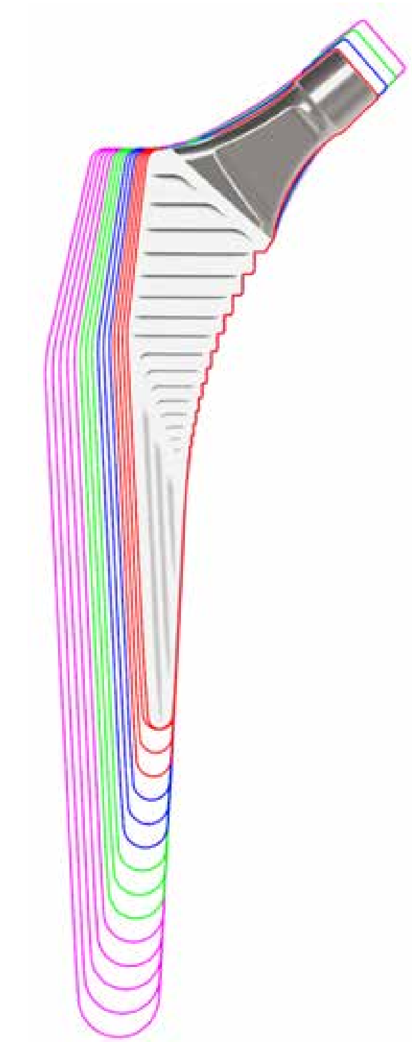
INCREMENTAL STEM SIZING

The surgeon design team and engineers felt that it was important to improve upon the stem size options available in the Alteon HA system compared to competitive designs. The incremental stem growth between sizes is smaller than previous generation's fully HA-coated, tri-taper stems. In addition, within the Alteon HA system, the stems grow in smaller increments in the smallest sizes where that finer resolution is believed to be more valuable. As a result, the Alteon HA system offers more sizes, versus some first-generation stems, to accommodate a comparable size femur and is designed to avoid potting in Type A Femora.

Alteon HA Femoral Stem
Neck Length Grouping and M/L Growth

Group 1 = Sizes 1, 2, 3, 4
Group 2 = Sizes 5, 6, 7
Group 3 = Sizes, 8, 9, 10
Group 4 = Sizes 11, 12, 13, 14*, 15*

**Items are special order.*

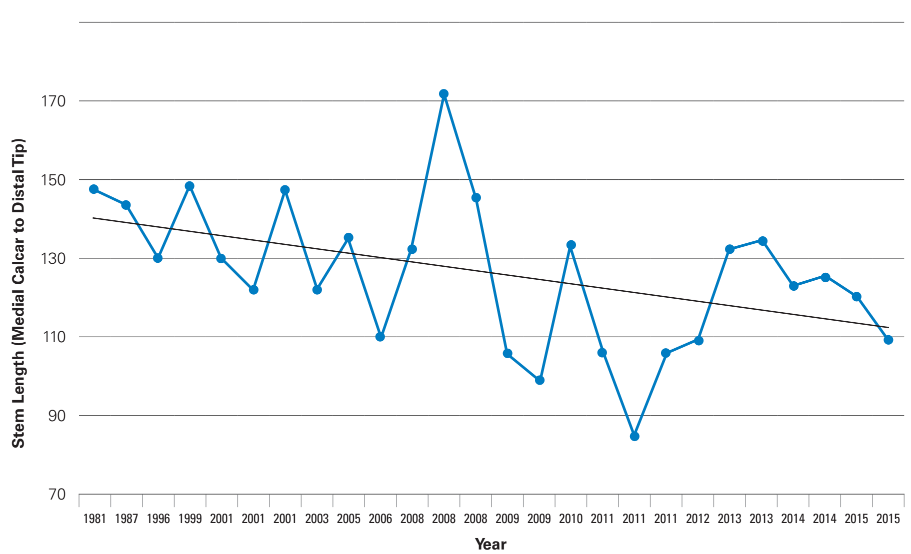


SHORTER OVERALL STEM LENGTH

Over the last 10 to 15 years, there has been an increase of the Direct Anterior Approach for hip replacement. A survey in 2016 from the American Association of Hip and Knee Surgeons (AAHKS) revealed 34 percent of surgeons surveyed utilize Direct Anterior Approach. This is a significant increase over the low single digits exhibited in the early 2000s.[9,16] The overall length of femoral stems has been arbitrarily reduced over time. As part of the design phase, four different femoral stem types (extensively-coated HA, fit-and-fill, tapered wedge and short stems) were analyzed from 10 different companies. Twenty-six brands were plotted based on FDA clearance date and average overall length. From 1981 until 2016, there was a reduction in average overall length by about five percent each decade, which can be seen in the graph below.[9] With this in mind, the overall length of the Alteon HA was designed to be within the range of currently marketed devices.

There are many available bone-conserving femoral designs that serve as an alternative treatment option to conventional total hip arthroplasty (THA), especially in young, active patients. Both stem length and design play an important role in primary implants. In particular, bone conserving designs, such as shorter stemmed femoral components, have potential advantages such as proximal bone preservation, greater ease of insertion, and more physiological bone remodeling.[17] When more proximal load transfer is achieved in the femur, it is likely this would reduce any possible thigh pain or stress shielding.

Sakai et al. (1999) investigated the relationship between stem length and canal filling on patients who underwent THA using a custom-made femoral component with two different stem lengths (125mm and 100mm). They found that a shorter stem better fills the canal of the femur at the distal level than the long stem.[18] Another study showed that, as stem length decreased, the stability of the implant was not substantially affected until it reached approximately 35 percent of the original length.[20] The Alteon HA stem's overall length was reduced by up to 25 percent compared to the DePuy Corail, with the length ranging from 94mm to 128mm.[9] In the x-ray to the right, this length comparison can be seen between Alteon HA and the DePuy Corail.



HA COATING

Hydroxyapatite ($Ca_{10}(PO_4)_6(OH)_2$) is an osteoconductive material which uses calcium and phosphate ions to promote bone ongrowth and help the bone to remodel.[19]

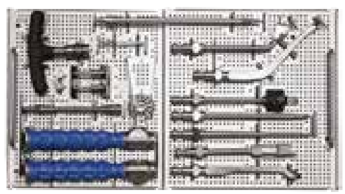
When the effect of coating thickness was tested by Svehla et al., they found that a 100 micron coating was better than a 50 micron coating, but 150 microns was no better than a 100-micron coating.[20] The Alteon HA is extensively coated with an 80μm-thick Hydroxyapatite (HA) coating which is designed to provide bone ongrowth in less than two weeks. Favorable results with more than 20 years of cumulative data have shown HA-coated devices to be an effective and reliable option in primary THA.[23]

- Extensive HA coating is designed to encourage femoral osseointegration while reducing thigh pain and risk of subsidence[23]
- Less likely to experience fatigue fracture[24]
- Clinically acceptable bioresorption rate[24]

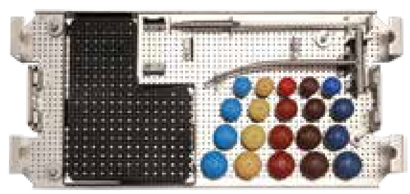
Instrument Design Features

PLATFORM INSTRUMENTATION

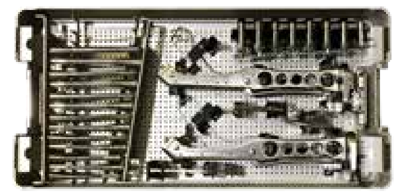
The Alteon HA is part of the Alteon family of hip products. This platform hip system features a set of common femoral instruments that can be used across multiple stems. The system features a consolidated two tray design regardless of surgeon approach to enhance operating room efficiency.



Core Femoral Tray (Upper)



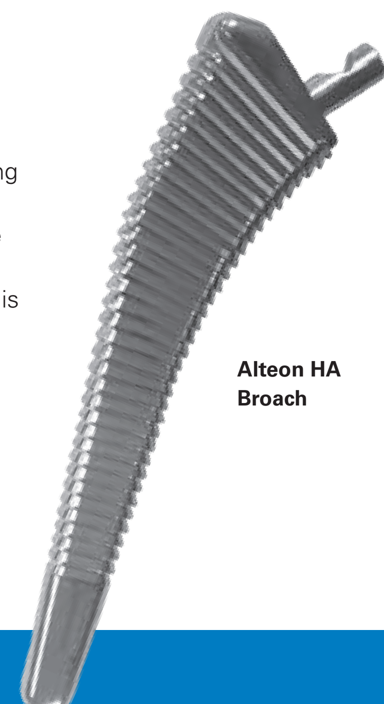
Core Femoral Tray (Lower)



Alteon HA Broach Tray

BROACH DESIGN

The Alteon HA broaches are compaction-style broaches designed to conserve bone while still enabling accurate preparation of the femoral cavity. Utilizing these broaches, the surgeon prepares the femur by compacting and reshaping, not removing the intramedullary bone, for optimal implant stability. The Alteon HA broaches are designed to provide a 155µm press-fit which allows for predictable implant seating.[9,17] When the HA prosthesis is impacted to an axial stopping point, the proximal border of the HA will be approximately 1.5mm above the final broach, depending on bone quality.



Alteon HA Broach

Conclusion

The Alteon HA is a next-generation, fully HA-coated, tri-taper stem. It incorporates specific philosophies and is designed to include subtle, yet significant design advancements over previous generation stems to improve surgical experiences and clinical outcomes.

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For additional device information, refer to the Exactech Hip System–Instructions for Use for a device description, indications, contraindications, precautions and warnings. For further product information, please contact Customer Service, Exactech, Inc., 2320 NW 66th Court, Gainesville, Florida 32653-1630, USA. (352) 377-1140, (800) 392-2832 or FAX (352) 378-2617.

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