ACUMED®

TECHNICAL MONOGRAPH

ANATOMIC RADIAL HEAD SYSTEM

INTRODUCTION (Reference 3-4,9)

Radial head fracture is the most common bony injury to the adult elbow.[4] Current and past designs of radial head prostheses have had a round radial head component. The radial head is clearly not round but has a more ellipsoidal shape.[4]

Designed in conjunction with Shawn O'Driscoll, PH.D., M.D., Acumed's Anatomic Radial Head Prosthesis is a unique implant that truly replicates the natural anatomy of the patient's radial head. Surgeons have emphasized the importance of restoring the biomechanical properties of the native radial head when radial head replacement is indicated.[9] Acumed's system restores the proper radial head geometry along with the proper height and placement in the radial canal.

Dr. O'Driscoll hypothesized that if he could not possibly fix the radial head then it should be replaced with a prosthesis that best replicates the anatomy of the patient. This improves "tracking" with the capitellum, reduction in implant loosening and thus results in a better patient outcome.

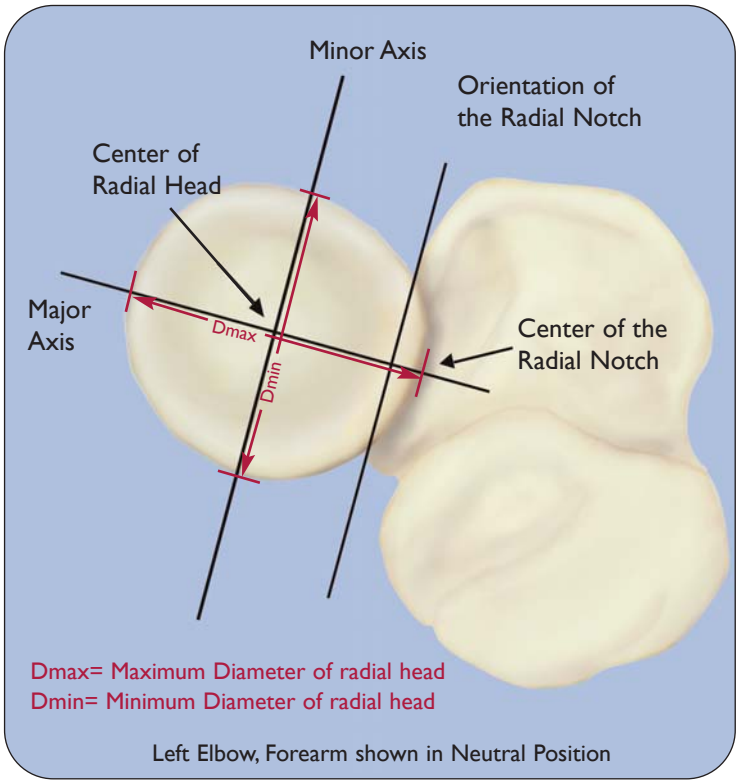
There are three potential areas of clinical importance of an anatomic (noncircular) radial head prosthesis: kinematics and stability, radiocapitellar contact forces, and stresses on the prosthesis-bone interface.[9]

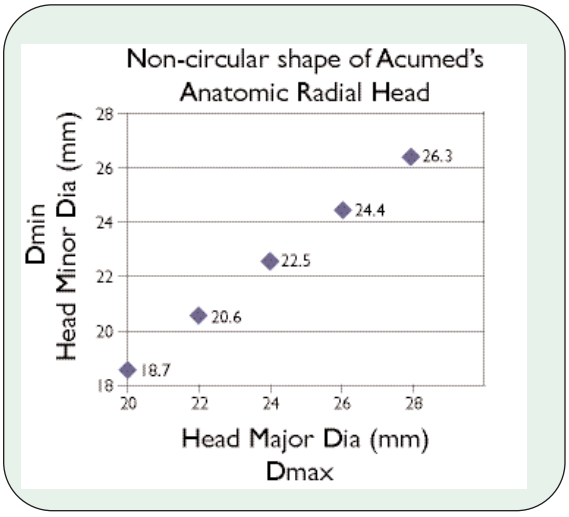
There is a growing concern among surgeons that suggests a need for an anatomic prosthesis. Because a round radial head prosthesis is non-anatomic, and therefore does not track perfectly against the capitellum, the altered kinematics could affect joint function and elbow stability. More importantly, eccentric loading potentially can alter radiocapitellar contact stresses leading to either insufficient or excessive load bearing. Finally, eccentric loading will increase stress on the prosthesis-bone interface, increasing the risk for loosening.[3]

HEAD DESIGN RATIONALE

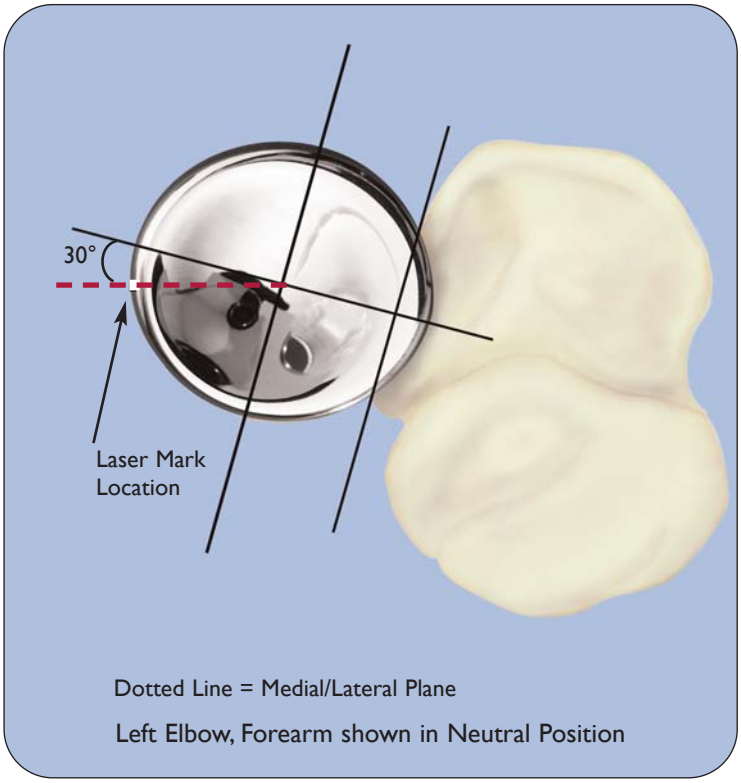
(Reference 1-5,10,11) ELLIPTICAL SHAPE

Acumed's Anatomic Radial Head Prosthesis features an ellipital-shaped head. Results of several studies, including an in-house study, have shown a strong correlation between the radial head's major diameter (Dmax) and minor diameter (Dmin) measured in cadaveric radial heads.[11] As shown in the figure to the right, the orientation of the major diameter axis is perpendicular to the radial notch when the forearm is neutral position.[1-5,10]





(Reference 4)

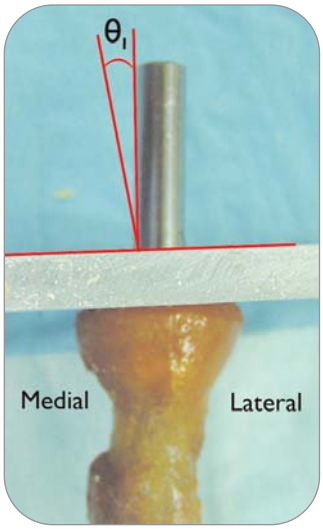


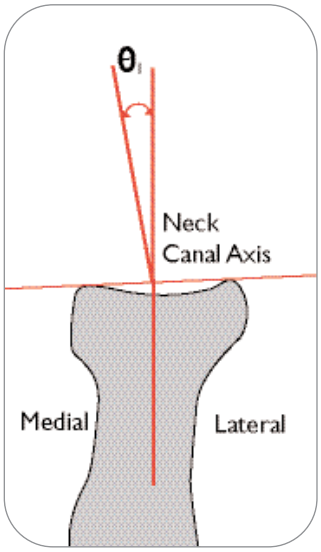
A laser mark on the prosthesis head and stem allows for proper alignment during assembly and insertion. The laser mark is located 30 degrees from the major axis. When inserting the prosthesis, the laser mark is then oriented lateral to the forearm in neutral position.[4]

HEAD DESIGN RATIONALE

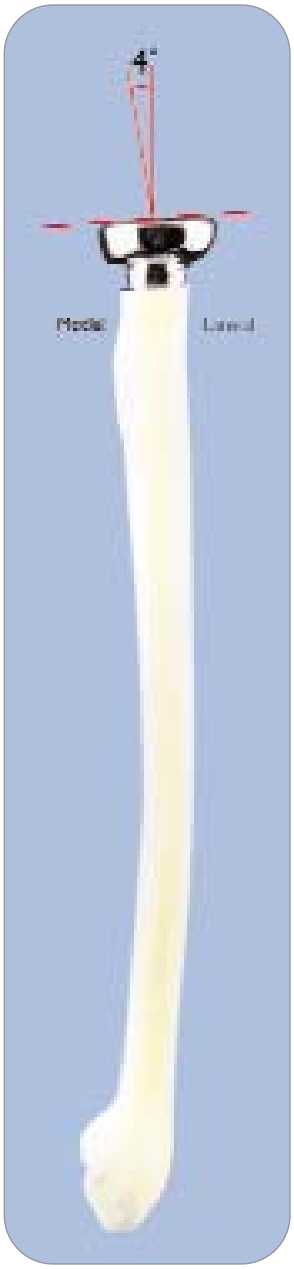
HEAD TILT (Reference 11)

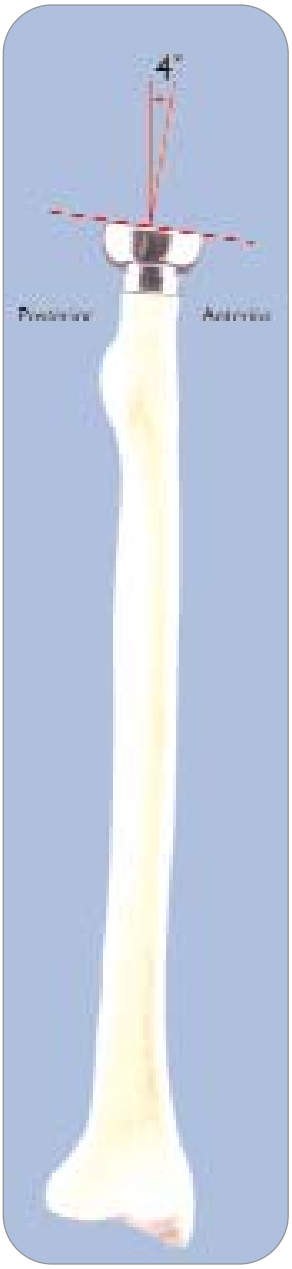
The Anatomic Radial Head was designed with 4 degrees of tilt in two planes: anterior/posterior and medial/lateral. The head tilt relative to canal axis was measured in 24 cadaver radii by drilling an oversized hole in the radial head and sequentially broaching until canal cortex met. The oversized hole allowed the broach to self align with the neck canal axis. A flat plate with a central hole was inserted over the broach and placed flat on top of the head. The angle of the head relative to the neck canal axis in the M/L plane (θ_1) and A/P plane (θ_2) was recorded along the major and minor axis. As a result of these measurements, a 4 degree M/L and A/P tilts were selected, thus creating a need for both left and right heads.[11]

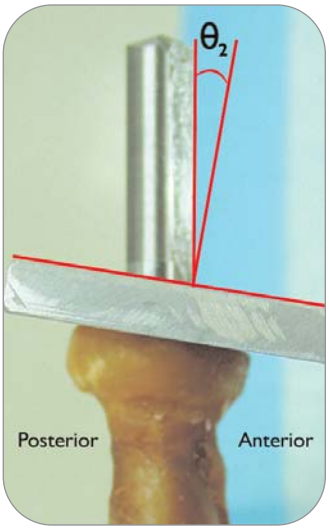


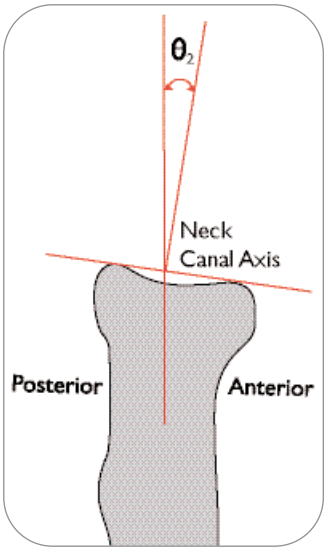


θ_1 = Medial/Lateral (M/L) tilt of head









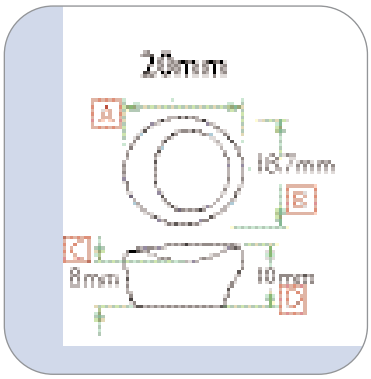
θ_2 = Anterior/Posterior (A/P) tilt of head

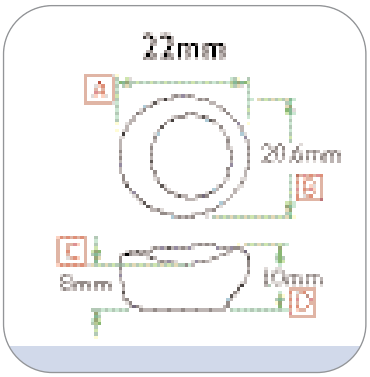
Left Radius Shown in Neutral Forearm Position

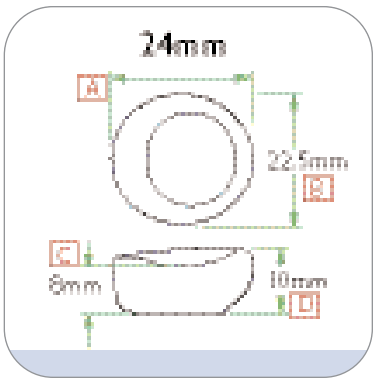
HEAD DESIGN RATIONALE

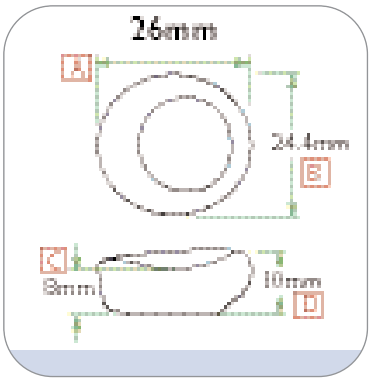
(Reference 3,5,6) OFFSET DISH

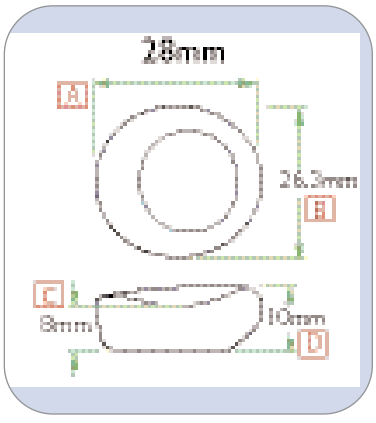
The dish is offset 1mm, from the center, in the lateral direction of the Anatomic Radial Head to properly accommodate the patient's anatomy. The dish depth is 2mm, and is consistent amongst all implant diameters. A head height of 10mm most closely replicates cadaveric radii. This was confirmed on the same 24 cadaver radii and in the referenced literature.[3,5,6]









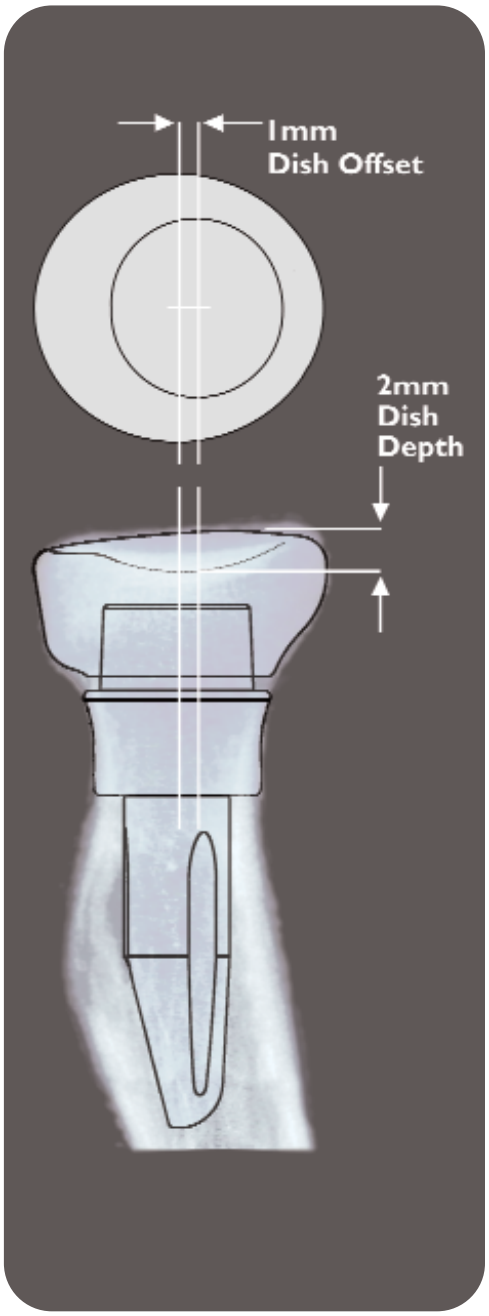


A = Maximum Diameter

B = Minimum Diameter

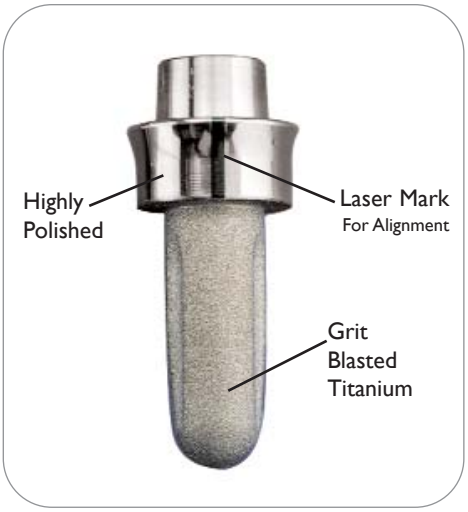
C = Height to Dish

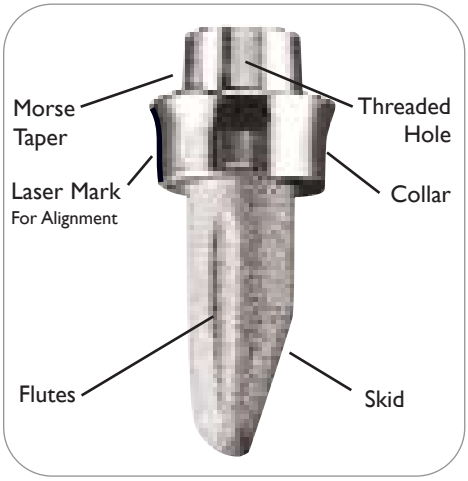
D = Head Height



STEM DESIGN RATIONALE

(Reference 7,8)



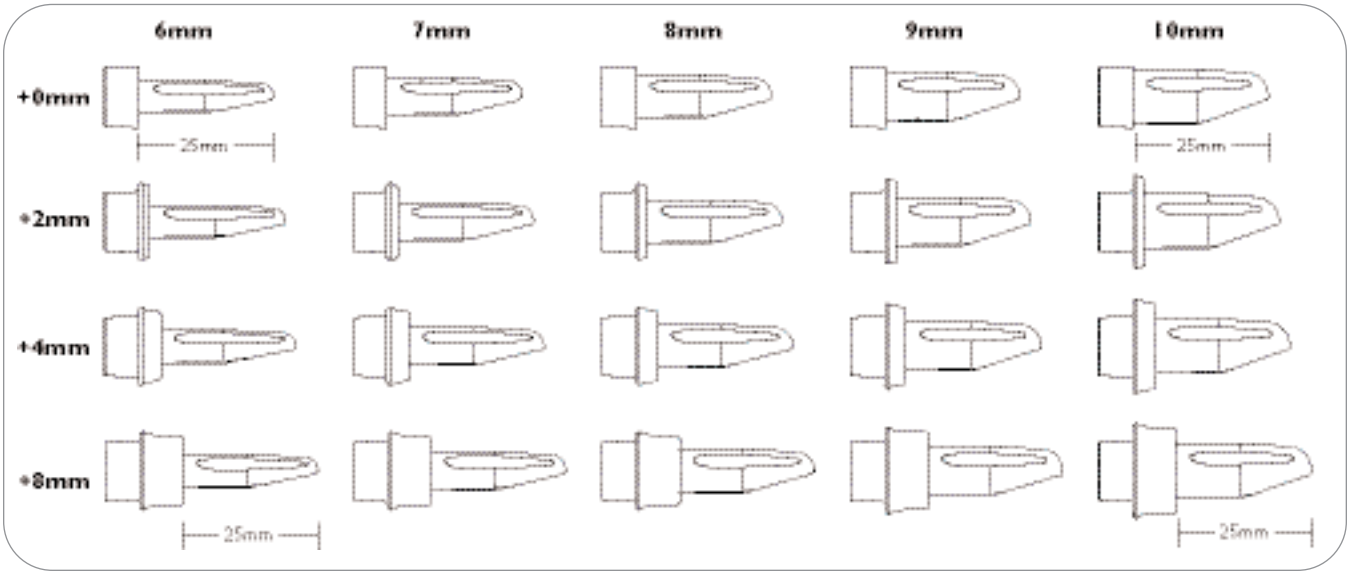


With the Anatomic Radial Head Prosthesis, height is restored by collar height, not the head height. Studies show that the length of the radial neck affects the valgus-varus position of the ulna throughout the flexion arc in each of the forearm rotations. Restoration of proper axial length of the radius is critical to avoid a number of complications such as residual instability.[7,8] The shape of the collar helps to restore the natural shape of the bone. The highly polished collar minimizes soft tissue irritation.

The stem is made from titanium alloy and is designed to press fit into the neck canal. A skid was placed on the tip of the stem, allowing for easier insertion and allows the stem length to be longer within the radial canal for stability and to resist loosening. The stem is grit blasted for bony ongrowth. Flutes are also added to the stem to allow for rotational stability upon bony ongrowth.

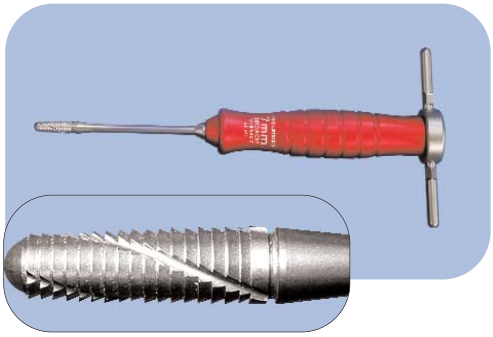
A Morse taper ensures a secure fit between the collar and the head, and 20 stem options give the surgeon a wide range of choices when choosing proper stem diameter and collar height.

A threaded hole is placed in the top of the stem to allow for implant removal when used in conjunction with the removal tool, included in the set.

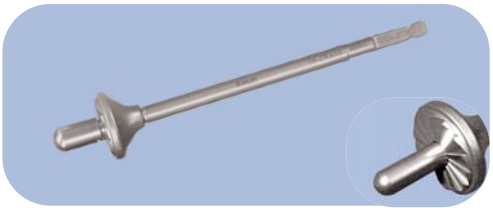


INSTRUMENTATION

The innovative broaches in the Anatomic Radial Head System allow the surgeon to create a precise opening in the radial canal for proper insertion of the implant. The broaches enter the radial canal in a straight direction and are less likely to broach the canal at an angle, resulting in improper implant placement. Spiral flutes on the broach are designed to displace bone during broaching. The implant stem is 0.5mm oversized from the broach diameter. The trial stem diameter is 0.5mm undersized of the broach diameter to allow for ease of trial insertion and removal. Side Pegs are provided for removal with a mallet and also provide a T-Handle for easy insertion and extraction. Broaches can be twisted back and forth and plunged into the radial canal or a mallet can be used to insert the broach. Furthermore, the broaches are color-coded for ease of trial implant selection.



Collar reamers are included in the system to create a perpendicular neck surface for the stem collar, allowing accurate placement of the stem.



A unique guide allows the surgeon to determine collar height. A sizing gauge is placed in the radial canal and then ratcheted proximally with the collar sizing gauge. The measurement corresponds to proper collar height, accurately restoring radial length.

TECHNICAL MONOGRAPH SUMMARY

While many fractures of the radial head are managed with conservative treatment, operative intervention is required for more complex fractures. The Acumed Anatomic Radial Head Prosthesis was designed to treat those fractures not amenable to internal fixation. During the design of the prosthesis, Dr. Shawn O'Driscoll hypothesized the following:

1) If perfect anatomy could be restored with rigid internal fixation that would be the best.
2) If we knew which aspects of the radial head shape and orientation were important, and if we could reproducibly position the prosthesis and assure fixation in the shaft, we might achieve #1.
3) Chances are that PERFECT replication of anatomy is not critical, but some elements are necessary.
4) With more research, we will determine which factors are critical.
5) Current trend of bipolar design is only necessary if we cannot achieve #4.

With 200 implant options and precise instrumentation, the Anatomic Radial Head System from Acumed is the first system that has design features that most closely replicate the patient's anatomy.

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11: Data on file

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