CUSTOM RADIAL HEAD IMPLANTS

The “Bioclone” Radial Head Custom Implant

- Surgical Grade Implantable Stainless Steel Material
- Unlimited Sizes Available
- Custom Anatomic Fit
- Less Expensive than off-the-shelf (approx. $800 – $1,000 less!!)
- Quick Delivery (3-7 days after receipt of X-Ray & Purchase Order)

We Design Each Implant to Fit Each Patient

“The custom implant philosophy has the metal conforming to the bone as opposed to the off-the-shelf implant which has the bone Surgically altered to meet the metal. In general regarding off-the-shelf implants, one size fits nobody, a few sizes fit a few, but no one size fits everybody. By contrast, Kapp Custom Implants are individually designed to fit the patient’s anatomic bone structure.”

William H. Seitz, Jr., M.D.
Cleveland Orthopaedic and Spine Hospital at Lutheran Cleveland Clinic Foundation
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PATENT PENDING
Introduction
The concept of radial head prosthetic replacement has gone through an evolution. Swanson developed a silastic replacement as a spacer following traumatic loss of the radial head. Experience has demonstrated the silastic radial head to be only a temporizing spacer at best with tendency to compress under axial loads and deteriorate in its integrity over time. Landsman and Seitz demonstrated inability of the silastic radial head to resist axial translation in the face of an Essex-Lopresti injury and demonstrated that either metallic radial head replacement or ligamentous reconstruction of the interosseous membrane was needed to resist displacement. (Journal of Orthopeadic Trauma, 9:516-522, 1995)

“Monoblock” radial head metallic prostheses have evolved, which are available “off-the-shelf” but given their size and dimensions and rigidity require excessive bone resection to insert and are technically demanding to use. As a result, modular prostheses have evolved with a number of stem and radial head sizes, usually in the “small, medium and large” category. Unfortunately as the length of the head increases so usually does the diameter. As a result, “one size fits nobody”

A talented surgeon can adapt these off-the-shelf prostheses to fit the anatomy of an acute fracture but it is not uncommon that even in experienced hands, the prosthesis does not achieve the stability desired. Based on the frustrations encountered trying to use silastic and “off-the-shelf” metallic radial heads, a system for “custom reproduction” of the radial head has been developed. This system provides custom broaches to insert the radial head, utilizes standard x-rays with standardized markers to provide a radial head with appropriate stem fit and depth to provide stability, using a slightly undersized diameter to afford adequate capsular and ligamentous closure. This obviates the necessity for “over-resection” required with use of the “unibody” prosthesis and the necessity to make the anatomy fit the prosthesis in the “small, medium and large” modular systems. Rather than making the anatomy fit the prosthesis, our philosophy is to fabricate a user-friendly custom-made prosthesis, which fits the anatomy.

Indications
Indications for use of the radial head prosthesis include radial head fracture not amenable to fixation, radio capitellar arthropathy due to degeneration or malunion of a radial head fracture, complex fracture dislocation of the elbow with loss of radial head support and Essex-Lopresti fracture-dislocation with loss of the radial head, rupture of the interosseous membrane and disruption of the distal radio ulnar joint. In these cases, Landsman and Seitz have shown silastic to be inadequate, metallic replacement to be stable and biologic reconstruction to be promising but unproven and with the potential for high degree of complications. The “off-the-shelf” prostheses which are available are relatively few and are extremely expensive. What the surgeon finds is that the limited available sizes fit no particular anatomy perfectly. In general one size fits nobody, a few sizes fit a few but no one size fits everybody. The question which must be asked is why not provide a custom prosthesis which is easy to insert and provides a degree of stability necessary for these complex injuries.
Custom Prosthesis Prescription and Fabrication
Custom design utilizes standard AP and lateral x-rays with a standardized marker. Custom blueprints are generated for prosthetic design matching intermedullary canal, the depth of the cut in the neck of the proximal radius and the diameter and height of the head. Head diameter is undersized by at least 2 mm compared to the anatomic size to allow adequate capsular closure which is important to achieve pronation and supination with stability. Comparison x-rays are obtained for the non-pathologic side to be able to generate an anatomic fit. The stem length and diameter provides an exact canal fit; the head height provides adequate axial stability while the diameter being 2 mm smaller than the anatomic head affords adequate closure of the capsular ligaments.

**STEP 1**
Surgical technique utilizes a direct lateral approach through the extensor digitorum communis muscle. Through this approach, the capsule and orbicular ligament are opened longitudinally.

- RCL - Radial Collateral Ligament
- AL - Annular Ligament
- LUCL - Lateral Ulnar Collateral Ligament

**STEP 2**
The radial head and neck are visualized and an oscillating saw is used to resect the radial head at a pre-determined level based on x-ray planning.

**STEP 3**
A customized broach is then utilized to prepare the canal (each prosthesis is delivered with its own broach anatomically conforming to the patient’s canal and to the custom prosthesis).

**STEP 4**
Once the canal has been broached, the prosthetic stem is inserted and impacted with a custom impactor until the collar is fully seated on the radial neck.

**STEP 5**
At this point the custom radial head is applied to the stem in standard modular technique.

Continue Step 6 & 7 on next page.
STEP 6
If there should be a sense that there is too tight a fit the prosthesis can be removed and additional millimeter of resection can be performed with the oscillating saw and the stem reinserted and the head reapplied. Conversely if the radial head is not felt to provide adequate lateral stability, a 1 and a 2 mm “collar spacer” are provided to take up the “slack” between the radial head and the stem.

STEP 7
Closure. Once the radial head is well inserted and lateral stability has been achieved, full pronation and supination have been confirmed, closure of the capsule is performed with a running suture of 3.0 non-absorbable braided polyester. The muscle fascia is approximated over this with a running simple suture of 3.0 or 2.0 braided polyester suture and the skin closed with an absorbable subcuticular running suture.

SURGICAL TECHNIQUE SUMMARY

1. Lateral approach
2. Open orbicular ligament
3. Resection neck at predetermined level
4. Broach canal
5. Insert stem
6. Apply head
7. Capsular closure

This technique has provided substantial enhancement of the fit of the radial head prosthesis offering the ease of surgical insertion at a substantial financial savings based on implant costs.

The technique is biomechanically well founded, provides enhanced fixation and stability with an increased technical ease of surgical implantation.

Sterilization tray with Broach and Impactor instruments on left and the Custom Radial Head Implant and Spacers enclosed on the right. After implantation into the patient, the instrument tray, broach and impactor instruments are returned to Kapp Surgical Instrument, Inc. within 48 hours, minimizing the cost of Custom Implant surgery.