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**Design Team**

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**Thomas Wright, MD**, Equinoxe® design team member and world renowned expert in shoulder surgery, specializes in upper extremity practice at University of Florida College of Medicine. He completed his residency at University of Florida and his fellowship in hand and upper extremity surgery at Mayo Clinic. Among many other accomplishments, Dr. Wright has earned 13 grants and refereed more than 110 published works.

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Introduction

The Equinoxe® Humeral Reconstruction Prosthesis (Figure 1) is designed for challenging shoulder arthroplasty cases with significant humeral bone loss.* This platform modular humeral stem was developed to be the definitive shoulder revision system to address the myriad of revision possibilities that may arise given the dramatic market growth of shoulder arthroplasty over the past 15 years (Figure 2). The Equinoxe Humeral Reconstruction Prosthesis integrates with the entire Equinoxe Shoulder System and allows the surgeon to have intra-operative flexibility to choose between hemiarthroplasty, anatomic total shoulder, or reverse shoulder arthroplasty.* Due to the varying levels of possible humeral resections, the midsections and proximal bodies have numerous locations for soft tissue attachment as well as a range of sizes to reconstruct the humerus in 12.5mm increments from 50 to 222.5mm in length. The anatomically shaped proximal bodies are designed to help reattach the rotator cuff muscle insertions at their anatomic location; these proximal bodies are provided in multiple thicknesses to increase deltoid wrapping and designed to improve joint stability. Additionally, the offset distal stem and offset diaphyseal collars are designed to provide external fixation and rotational stability while ensuring an optimal fit and uniform cement mantle within the intramedullary canal. It should be noted that shoulder reconstructions are challenging procedures, particularly when those revisions are associated with significant humeral bone loss; these procedures should only be performed by surgeons with significant experience. Exactech's medical education program featuring fellowship trained shoulder specialists and oncologists can help surgeons gain that experience using this reconstruction prosthesis.

*The Equinoxe Humeral Reconstruction Prosthesis is not indicated for use with the reverse shoulder components in oncology applications.
Design History and Evolution of Humeral Endoprosthetic Designs

Before limb salvage techniques, the standard of care was amputation. Endoprostheses were designed originally with a goal to treat tumors where the resection compromised a large segment of the bone. It was first described in the femur by Moore in 1943 (Figure 3). The first humeral endoprosthesis (including humeral head and diaphysis) was implanted in 1950 at the Royal National Orthopedic Hospital.10

Figure 2
Estimated procedural distribution and usage of shoulder arthroplasty in the United States (2003 to 2015P) using the most recent ICD-9/discharge data from the National Inpatient Sample (NIS), Healthcare Cost and Utilization Project (HCUP), and Agency for Healthcare Research and Quality databases7

Figure 3
First endoprosthesis femur – Moore 194312
The use of endoprostheses did not expand until the development of adjunct therapies to treat cancer and stop/reduce the reoccurrence of tumors. This was described in the 1970s when several investigators performed segmental endoprosthetic reconstruction in patients who had tumors thought to be untreatable with resection (Figure 4).\textsuperscript{9,11-13} As chemotherapy and radiation treatment improved the outcomes of cancer patients, musculoskeletal oncologists began to see an increase in candidates for endoprosthetic treatment. This increase highlighted the need for modular systems that can treat a wide variety of bone geometries and resection lengths. Salzer first described a modular humeral prosthesis in 1979\textsuperscript{21} (Figure 5), and in 1988, Stryker Howmedica released a modular replacement system that is still in use at the time of this publication\textsuperscript{11,13} (Figure 6a).
Summary of Clinical Experience

Quantifying the clinical success of endoprostheses is difficult due to their usage in high-risk/limited goal patient populations that represent a very small number of cases. Additionally, studies tend to combine several uses, such as trauma, salvage/revision reconstruction and oncology. While the endoprostheses was originally designed for use in oncology settings, the versatility of such modular prostheses has expanded its use to salvage/complex revision procedures that are unrelated to oncology. Multiple journal articles have described the use of an endoprosthesis for non-tumor limb salvage and concluded that the use of an endoprosthesis appeared to be an effective medium- to long-term treatment option.12,22 As described in Table 1, humeral endoprostheses have shown mixed clinical results23-31 (Table 1). In McGrath’s 10-year review of 13 patients, the survival rate was less than 50 percent.24 Short term follow-up studies have reported 70-95 percent survival rates.27-29 These modest survival rates suggest that the market is underserved and that there are many areas of improvement needed with endoprosthesis design.

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Journal</th>
<th>Implant Detail</th>
<th>Follow-Up</th>
<th>N</th>
<th>Survival Rate of Implant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wang25</td>
<td>2015</td>
<td>International Orthopedics</td>
<td>Endoprosthesis with Poly Mesh</td>
<td>16</td>
<td>88%</td>
<td></td>
</tr>
<tr>
<td>Puri26</td>
<td>2012</td>
<td>JBJS Brit</td>
<td>Total Humerus</td>
<td></td>
<td>95%</td>
<td></td>
</tr>
<tr>
<td>Cannon27</td>
<td>2009</td>
<td>JSES</td>
<td>Proximal Humerus</td>
<td>30 mos</td>
<td>83</td>
<td>98%</td>
</tr>
<tr>
<td>Wedin28</td>
<td>2012</td>
<td>JSES</td>
<td>Proximal Humerus</td>
<td>35</td>
<td>94%</td>
<td></td>
</tr>
<tr>
<td>McGrath24</td>
<td>2011</td>
<td>Acta Orthop Belg</td>
<td>Proximal Humerus</td>
<td>10 years</td>
<td>13</td>
<td>47%</td>
</tr>
<tr>
<td>Raiss30</td>
<td>2010</td>
<td>Eur J Surg Oncol</td>
<td>Proximal Humerus</td>
<td>30 mos</td>
<td>39</td>
<td>72%</td>
</tr>
<tr>
<td>Kumar30</td>
<td>2003</td>
<td>JBJS Brit</td>
<td>Proximal Humerus</td>
<td>108 mos</td>
<td>47</td>
<td>87%</td>
</tr>
<tr>
<td>Shehadeh23</td>
<td>2010</td>
<td>Clin Orthop Res</td>
<td>Proximal Humerus</td>
<td>10 years</td>
<td>46</td>
<td>80%</td>
</tr>
<tr>
<td>Gosheger31</td>
<td>2006</td>
<td>Clin Orthop Relat Res</td>
<td>Proximal Humerus</td>
<td>45 mos</td>
<td></td>
<td>90%</td>
</tr>
</tbody>
</table>
The original endoprosthesis designs were limited by poor manufacturing techniques and use of insufficiently strong materials causing an unacceptably high failure rate of the stem. As new materials and manufacturing processes emerged for use in orthopaedics, improvements were observed in both strength and reliability of these metal implants. However, endoprosthetic designs have been relatively unchanged since the 1980s, as demonstrated by the fact that the Stryker Howmedica GMRS prosthesis is still on the market at the time of this publication with very few design improvements since its original launch in 1988\(^1\)\(^{11}\), (Figure 6b). Aseptic loosening, soft tissue fixation and joint instability are the most common failure modes associated with endoprostheses.\(^9\),\(^{11},\)\(^{14}\),\(^{23}\) In the 1990s, endoprosthetic usage became more accepted. Henderson et al.\(^9\),\(^{32}\) reported on endoprosthesis failures and developed a classification method to describe these failure modes. The failure classification is identified as five types: soft tissue (T1), aseptic loosening (T2), structural failure (T3), infection (T4) and tumor progression (T5).\(^32\)

Palumbo et al. presented a retrospective review that showed soft tissue failure accounting for 28.7 percent of all failures, and aseptic loosening accounting for 19 percent of all failures.\(^9\) Soft tissue challenges occurred because endoprostheses generally required reattachment of tendons directly to the metal implant. When tendons were attached to these implants, they were generally secured through fibrous growth, which has <20 percent of the strength of a normal tendon.\(^18\) Soft tissue failure can lead to joint instability and reduced function.

The high rate of complications associated with endoprostheses used with large humeral resections and revisions (in cases of proximal bone loss) suggests that there is an unmet clinical need for improved joint stability. The rotator cuff muscles and deltoid are the stabilizing muscles within the shoulder; when clinical situations are presented that result in loss of these muscle insertions, there is an increased risk of joint instability. Reverse shoulders have been demonstrated to provide stability and function when used with irreparable cuff tears. A platform shoulder reconstruction prosthesis design that can offer soft tissue fixation options while enhancing the joint biomechanics provides a viable alternative to currently marketed designs—with additional potential benefits that may reduce the rates of the complications mentioned above.
Exactech Design Philosophy

- Modularity
- Biomechanics
- Rotational stability
- Soft tissue reattachment

**MODULARITY**

Recent journal articles describe the use of reverse shoulder arthroplasty for treatment of bone loss or humeral resections. The Exactech platform shoulder system has been on the market since November 2004, and more than 60 papers focusing on it have been published in the last 10 years. The platform system offers the ability to use a reverse, hemi, or anatomic total shoulder arthroplasty with the same humeral stem component. With the Humeral Reconstruction Prosthesis design, we attempted to provide a solution for patients with proximal humeral bone loss and also for primary oncology applications. The need to treat these different patient issues with a reverse, hemiarthroplasty or anatomic total shoulder arthroplasty—and the ability to treat multiple resection heights (from 50 to 222.5) (Figure 8)—were driving forces behind this modular humeral stem prosthesis design.
BIOMECHANICS

Exactech utilized the latest research on the relationship between humeral stem design and shoulder biomechanics to develop this novel prosthesis. This led us to develop a unique anatomically shaped proximal body in multiple sizes to increase humeral lateralization and deltoid wrapping, improving joint mechanics and stability. In doing so, Exactech created an alternative method to tension a reverse shoulder prosthesis, which increases joint compression by additional deltoid wrapping around the proximal humerus (Figure 9), while also increasing the deltoid abductor moment arm to improve deltoid muscle efficiency without having to increase rotator cuff muscle tension (which occurs in the traditional method of using thicker humeral trays) (Figure 10).20

Figure 9
Tensioning the shoulder with small (left) and extra large (right) sizes of the proximal bodies. Thicker size proximal bodies increase deltoid wrapping, improve deltoid moment arm length and increase joint compression/stability.

Figure 10
Traditional method of utilizing a thicker humeral tray/liner to tension an unstable reverse shoulder prosthesis, elongating both the deltoid and the remaining rotator cuff musculature.20
As background, the compression forces in the shoulder are applied by the deltoid and rotator cuff muscles. Roche et al. reported on the deltoid wrapping angles of three different reverse shoulder prostheses and demonstrated that increased humeral lateral offset was associated with increased deltoid wrapping and more anatomic rotator cuff muscle tension. As the humerus is lateralized, the deltoid maintains its wrap around the greater tuberosity with humeral elevation to facilitate additional joint compression. Reduced wrapping is associated with reduced joint compression and also an increased risk of instability (Figure 11). Similarly, Henninger et al. studied the effect of humeral lateralization on dislocation forces in the lateral and anterior plane. They reported that there was a stepwise increase in the forces required for dislocation with increased lateral offset (Figure 12).

Figure 11
Joint compression achieved with deltoid wrapping. From left to right: deltoid wrapping achieved with the normal anatomic shoulder, less deltoid wrapping achieved with the medialized-humerus Grammont reverse shoulder, and additional deltoid wrapping achieved with the lateralized-humerus Equinoxe reverse shoulder.

Figure 12
Improved resistance to joint distraction with greater amounts of humeral lateralization.
Exactech developed the anatomic shape of this novel proximal body based upon the results of a CT reconstruction anatomic study of 74 cadavers (37 male and 37 female). From the range of observed proximal humeral measurements for both male and female humeri (Table 2), we created four proximal body options (small, medium, large, and extra large) having anterior-posterior widths (Figure 13) and lateral tuberosity widths (Figure 14) to simulate the varying proximal humerus morphologies.

Table 2: Comparison of Average Humeral Measurements: Female vs. Male

<table>
<thead>
<tr>
<th>Anatomic Parameter (mm unless noted)</th>
<th>All Humeri</th>
<th>Female</th>
<th>Male</th>
<th>P Value (Male vs Female)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Center of HH to Lesser Tuberosity</td>
<td>25.3 ± 3.5</td>
<td>22.9 ± 2.7</td>
<td>27.8 ± 2.2</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Center of HH to Greater Tuberosity</td>
<td>22.4 ± 2.7</td>
<td>21.1 ± 2.5</td>
<td>23.8 ± 2.1</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Overall Width</td>
<td>47.7 ± 5.1</td>
<td>43.9 ± 3.4</td>
<td>51.6 ± 3.2</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Figure 13
Anterior/posterior width ranges for the four sizes (left to right: small, medium, large and extra large) of proximal bodies utilized in the Equinoxe Humeral Reconstruction Prosthesis

Figure 14
Lateral tuberosity ranges for the four sizes (left to right: small, medium, large and extra large) of proximal bodies utilized in the Equinoxe Humeral Reconstruction Prosthesis
Rotational stability and adequate distal fixation are concerns with endoprostheses because these implants require fixation in the diaphyseal bone with little proximal bone support. A primary design goal for the Humeral Reconstruction Prosthesis was providing a prosthetic solution that could improve fixation in both oncology and revision applications without proximal bone support. A study quantifying the rotational stability of cemented vs. press-fit designs in the hip demonstrated significantly better initial fixation in the cemented design. However, the market has trended towards using implants with increased potential for osteointegration. As a result, Exactech’s implant design utilizes a cemented distal stem, with supplemental fixation provided by a hydroxyapatite press-fit diaphyseal collar. The addition of this collar substantially increases the moment arm of the distal fixation (Figure 15) to resist the internal rotation torque applied to this device during activities of daily living (Figure 16). As described in Table 3, bench testing demonstrated that this novel collar, coupled with the cemented distal stem, demonstrated significantly greater torsional resistance in both the torque to initial slip (29.4 vs. 8.2 Nm; p=0.0002) and the maximum torque to failure (44.3 vs. 12.1 Nm; p<0.0001) compared to a different distally cemented stem without supplemental collar support.

**Table 3:** Torque to initial slip and the peak torque to failure associated with the Humeral Reconstruction Prosthesis, compared to a standard cemented long stem without collar

<table>
<thead>
<tr>
<th>Sample</th>
<th>Humeral Reconstruction Prosthesis</th>
<th>Cemented Humeral Long Stem</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Torque to Initiate Slipping (N-m)</td>
<td>Maximum Torque (N-m)</td>
</tr>
<tr>
<td>1</td>
<td>22.6</td>
<td>48.5</td>
</tr>
<tr>
<td>2</td>
<td>34.3</td>
<td>49.4</td>
</tr>
<tr>
<td>3</td>
<td>24.2</td>
<td>39.0</td>
</tr>
<tr>
<td>4</td>
<td>35.7</td>
<td>45.4</td>
</tr>
<tr>
<td>5</td>
<td>29.4</td>
<td>39.2</td>
</tr>
<tr>
<td>Average</td>
<td>29.4 ± 5.9</td>
<td>44.3 ± 5.0</td>
</tr>
<tr>
<td>P Value (comparison of stems)</td>
<td><strong>0.0002</strong></td>
<td><strong>&lt;0.0001</strong></td>
</tr>
</tbody>
</table>
The distal collar sizing and scope were based upon the results of the CT anatomic reconstruction study of 74 cadaveric shoulders mentioned previously.\textsuperscript{1} The distal collars are provided in 17 sizes ranging from 17.5mm to 33.5mm in 1mm increments. The CT anatomic reconstruction study quantified both the outer diaphyseal diameter and the inner intramedullary diameter as well as the offset between the two diameters at multiple locations from the top of the humeral head (75mm, 150mm, 225mm) and at the deltoid tuberosity (Figure 17). As described in Table 4, the average outer diameter sizes ranged from 19.2mm to 23.1mm at 225mm and 75mm, respectively.

![Figure 17](image-url)

**Figure 17**
Humeral intramedullary and diaphyseal measurements from the CT scan reconstruction study\textsuperscript{23}

**Table 4: Comparison of Average Humeral Diaphyseal Measurements: Female vs. Male\textsuperscript{1}**

<table>
<thead>
<tr>
<th>Anatomic Parameter (mm unless noted)</th>
<th>All Humeri</th>
<th>Female</th>
<th>Male</th>
<th>P Value (Male vs Female)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humeral IM Diameter (75mm)</td>
<td>14.0 ± 3.0</td>
<td>11.9 ± 2.1</td>
<td>16.2 ± 2.1</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Humeral Outer Diameter (75mm)</td>
<td>23.1 ± 3.5</td>
<td>20.4 ± 2.2</td>
<td>25.8 ± 2.4</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Humeral IM Diameter (Deltoid Insertion)</td>
<td>10.6 ± 2.4</td>
<td>9.4 ± 2.0</td>
<td>11.7 ± 2.1</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Humeral Outer Diameter (Deltoid Insertion)</td>
<td>21.4 ± 2.9</td>
<td>19.2 ± 1.8</td>
<td>23.5 ± 1.9</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Humeral IM Diameter (150mm)</td>
<td>10.4 ± 2.4</td>
<td>9.2 ± 1.8</td>
<td>11.5 ± 2.4</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Humeral Outer Diameter (150mm)</td>
<td>21.4 ± 2.9</td>
<td>19.2 ± 1.9</td>
<td>23.7 ± 1.9</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Humeral IM Diameter (225mm)</td>
<td>9.1 ± 1.9</td>
<td>8.5 ± 1.6</td>
<td>9.8 ± 1.9</td>
<td>0.0030</td>
</tr>
<tr>
<td>Humeral Outer Diameter (225mm)</td>
<td>19.2 ± 2.6</td>
<td>17.1 ± 1.7</td>
<td>21.2 ± 1.6</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Offset Between IM and Outer Diameters (Deltoid Tuberosity)</td>
<td>0.9 ± 0.5</td>
<td>0.8 ± 0.5</td>
<td>1.0 ± 0.5</td>
<td>0.1925</td>
</tr>
<tr>
<td>Offset Between IM and Outer Diameters (75mm)</td>
<td>0.8 ± 0.5</td>
<td>0.8 ± 0.4</td>
<td>0.9 ± 0.5</td>
<td>0.2683</td>
</tr>
<tr>
<td>Offset Between IM and Outer Diameters (150mm)</td>
<td>0.9 ± 0.6</td>
<td>0.8 ± 0.4</td>
<td>1.1 ± 0.7</td>
<td>0.0401</td>
</tr>
<tr>
<td>Offset Between IM and Outer Diameters (225mm)</td>
<td>0.6 ± 0.3</td>
<td>0.5 ± 0.3</td>
<td>0.6 ± 0.3</td>
<td>0.0659</td>
</tr>
</tbody>
</table>
Dual Offsets of the Diaphyseal Collar and the Distal Stem

As described in Table 4, the results of the anatomic study demonstrated that the average offset between the diaphyseal humeral diameter and the intramedullary axis varied between 0.6–0.9mm at resection heights of 225mm, and the deltoid tuberosity to 75mm, respectively. As a result of these findings, both the distal stem and diaphyseal collar each incorporate a 1mm offset to allow for the combined dual offset of the devices to account for 0-2mm in anatomic variability (Figures 18 and 19). This dual offset ensures adequate fit of the collar around the humeral diaphysis while also ensuring that the distal stem is centered within the intramedullary canal to provide a uniform cement mantle thickness (Figure 20).
METHODS OF SOFT TISSUE REATTACHMENT

The design of the Equinoxe Humeral Reconstruction Prosthesis utilizes numerous suture holes and regions of plasma coating located on the proximal bodies and middle segments to facilitate soft tissue reattachment by a variety of methods (Figure 21) as supported by the literature.10,19,33,36-49 The locations of plasma coating provide surgeons with options for soft tissue reattachment at anatomic locations or muscle transfers in cases where it is deemed necessary for stability and function. Titanium plasma spray, as utilized in other common endoprosthesis designs, provides a rougher surface which may facilitate this fixation using the various methods presented in the literature. Specifically, the literature reports that successful outcomes can be achieved using multiple endoprostheses with soft tissue reattachment by the use of Dacron/mersilene tape or nonabsorbable sutures8,19,38,39,44,45,48 either directly to the prosthesis or via Gortex, Trevira tubes, or other artificial cardiovascular grafts.19,41,43,47 Additionally, bone graft can be secured around the prosthesis to facilitate soft tissue to the prosthesis through the graft.35-40,42,44,46,49 If the surgeon does not think that the tissue is of sufficient quality or length to secure to the prosthesis by these methods, soft tissue can be secured to other surrounding soft tissue groups unaffected by the resection, combining muscle groups to provide static support and greater joint closure.19,33

Conclusion

The Equinoxe Humeral Reconstruction Prosthesis represents the next generation of treatment for proximal humeral bone loss in the shoulder. This prosthesis is currently the only device cleared by the FDA for use in hemi, anatomic total and reverse total shoulder arthroplasty with proximal humeral bone loss. As surgeons perform more reverse procedures and observe more situations where proximal bone loss occurs or resections are required, only Exactech can provide solutions to treat these real clinical challenges. The Equinoxe platform shoulder system has a history of more than 10 years of clinical use, and the addition of the Humeral Reconstruction Prosthesis further differentiates this robust product offering to better address the many different clinical challenges that can arise when performing revisions and/or arthroplasty with significant bone loss.
Radiographic Outcomes

CASE 1
This patient had a comminuted spiral fracture all the way down the arm, a recently cleared infection, a severely eroded glenoid and an irreparable rotator cuff tear. This was the sixth surgery the patient had undergone, and as a result, there was significant scar tissue. As depicted in the attached immediate post-op x-ray, the surgeon secured a 19.5mm collar around the humeral diaphysis with a 7x80mm humeral stem to obtain distal fixation. The surgeon then secured the bone fragments with the deltoid tuberosity around a 75mm middle segment to achieve soft tissue stability and attached the small proximal body to build the prosthesis to a length that restores the patient’s original humeral length. The surgeon completed this reverse total shoulder by utilizing an expanded glenosphere with an augmented baseplate to obtain glenoid fixation while lateralizing the joint line to achieve sufficient deltoid wrapping and joint stability (Figure 22).

CASE 2
This patient had a well-fixed Biomet stem in place. The stem was implanted proud and presented with severe stress shielding on the lateral side, resulting in metadiaphyseal bone loss. The surgeon performed a reverse total shoulder using a posterior augment baseplate, 42mm glenosphere and 0mm humeral tray and liner. The humeral reconstruction required a small proximal body with a 22.5mm collar and a 9x80mm stem (Figure 23).

CASE 3
This patient had a proximal humerus fracture and was treated with an Equinoxe platform fracture stem. The patient presented with a periprosthetic fracture at the tip of the implant and severe proximal bone loss. The surgeon used the Humeral Reconstruction Prosthesis with a reverse to treat this patient. The surgeon used a 9x80mm stem, 18.5mm collar, 75mm midsection and a small proximal body (Figure 24).
References


Revision cases can be complex and challenging. Exactech’s latest revision products for hip, knee and shoulder are designed to deliver ease of use for surgeons and improved outcomes for patients. Whatever demands you face in the O.R., Exactech products can help you address them. **Complexity Simplified.**