



EXACTECH | SHOULDER

Design Rationale



equinox[®]
PLATFORM SHOULDER SYSTEM

Humeral Reconstruction Prosthesis

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Humeral Reconstruction Prosthesis

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Design Team



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Parker Gibbs, MD, is professor of orthopaedic surgery at University of Florida College of Medicine. He completed his internship and residency in general surgery at University of Colorado and fellowships in orthopaedic oncology at University of Chicago. Dr. Gibbs' research has been published in multiple books and journals, and he is an accomplished lecturer.



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Mark Scarborough, MD, is chairman of the department of orthopaedic surgery and rehabilitation and chief of the division of orthopaedic oncology at University of Florida. He completed his internship and residency at University of Texas Medical Branch and his fellowship in orthopaedic oncology at Massachusetts General and Boston Children's Hospitals.



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.



Joseph Zuckerman, MD, is professor and chairman, and surgeon-in-chief at NYU Hospital for Joint Diseases. He completed his internship and residency at University of Washington, and fellowships at Brigham and Women's Hospital and Mayo Clinic. Dr. Zuckerman is an industry thought leader and has traveled around the world educating surgeons on shoulder replacement. He is past president of the AAOS and an Equinoxe® design team member.



Introduction

The Equinox® 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 Equinox Humeral Reconstruction Prosthesis integrates with the entire Equinox 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 shaped¹ 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^{3-6,17} 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 Equinox Humeral Reconstruction Prosthesis is not indicated for use with the reverse shoulder components in oncology applications.*



Figure 1
Equinox Humeral
Reconstruction Prosthesis

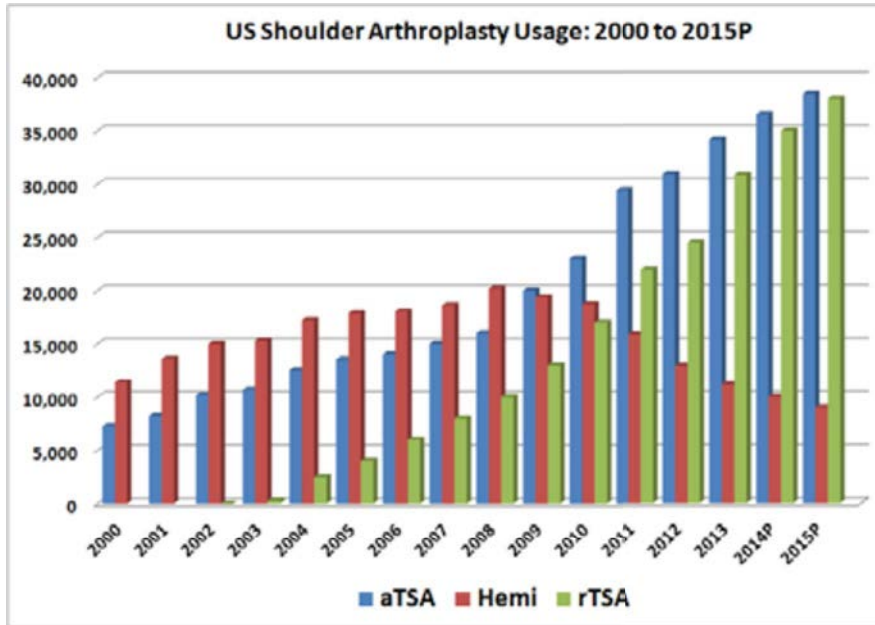


Figure 2

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

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*).¹² The first humeral endoprosthesis (including humeral head and diaphysis) was implanted in 1950 at the Royal National Orthopedic Hospital.¹⁰



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*).^{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 1979²¹ (*Figure 5*), and in 1988, Stryker Howmedica released a modular replacement system that is still in use at the time of this publication^{11,13} (*Figure 6a*).



Figure 4
Implant used for segmental endoprosthetic reconstruction (1970s)¹³



Figure 5
First reported modular humeral prosthesis (Salzer, 1979)²¹



Figure 6a
Stryker Howmedica GMRS modular design introduced in 1988¹³

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 endoprosthesis 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 1: Reported Clinical Success of Humeral Endoprostheses

Author	Year	Journal	Implant Detail	Follow-Up	N	Survival Rate of Implant
Wang ²⁵	2015	International Orthopedics	Endoprosthesis with Poly Mesh		16	88%
Puri ²⁶	2012	JBJS Brit	Total Humerus			95%
Cannon ²⁷	2009	JSES	Proximal Humerus	30 mos	83	98%
Wedin ²⁸	2012	JSES	Proximal Humerus		35	94%
McGrath ²⁴	2011	Acta Orthop Belg	Proximal Humerus	10 years	13	47%
Raiss ²⁹	2010	Eur J Surg Oncol	Proximal Humerus	38 mos	39	72%
Kumar ³⁰	2003	JBJS Brit	Proximal Humerus	108 mos	47	87%
Shehadeh ²³	2010	Clin Orthop Res	Proximal Humerus	10 years	46	80%
Gosheger ³¹	2006	Clin Orthop Relat Res	Proximal Humerus	45 mos		90%

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^{11,13} (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.



Figure 6b
Stryker Howmedica
GMRS modular design
introduced in 1988

Exactech Design Philosophy

- Modularity
- Biomechanics
- Rotational stability
- Soft tissue reattachment



Figure 7
Equinox Humeral
Reconstruction Prosthesis



Figure 8
Equinox Humeral Reconstruction Prosthesis
configurations to reconstruct the humerus
from 50 to 222.5mm in length

MODULARITY

Recent journal articles describe the use of reverse shoulder arthroplasty for treatment of bone loss or humeral resections.^{8,42} 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 (*Figure 7*), 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

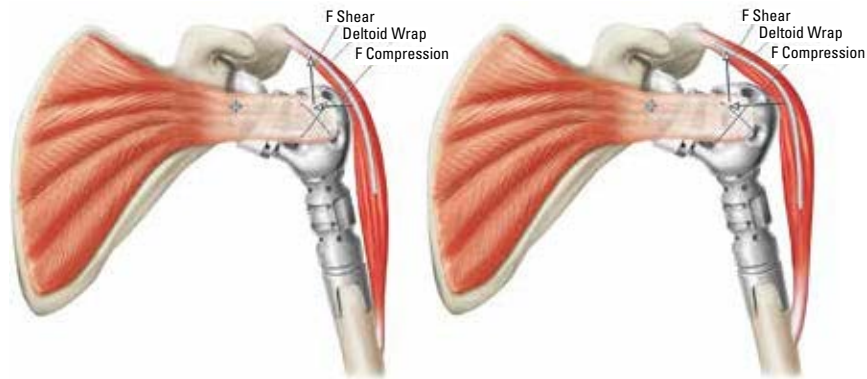


Figure 9

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.

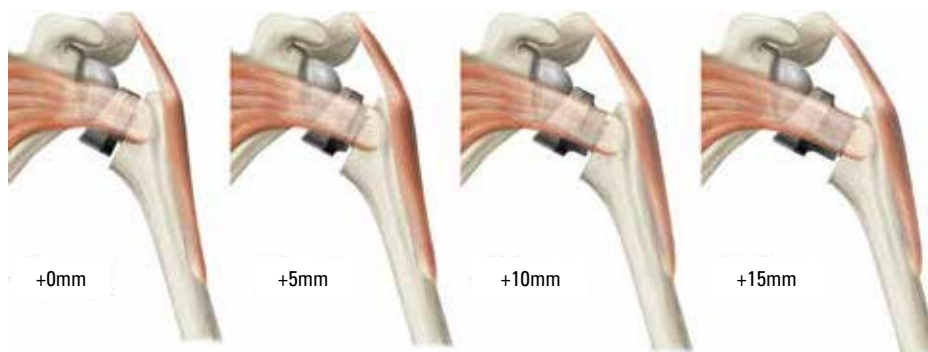


Figure 10

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.⁴ 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.¹⁷ They reported that there was a stepwise increase in the forces required for dislocation with increased lateral offset (*Figure 12*).²²

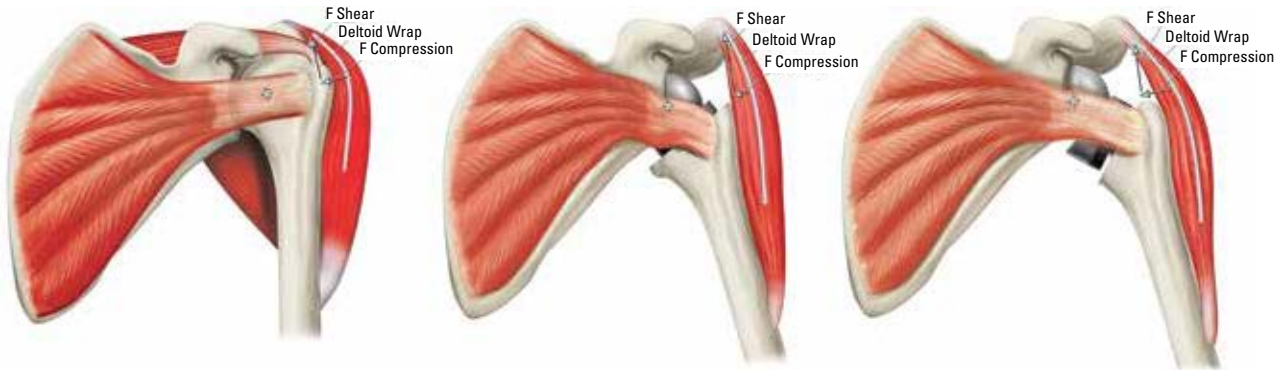


Figure 11

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 Equinox reverse shoulder.

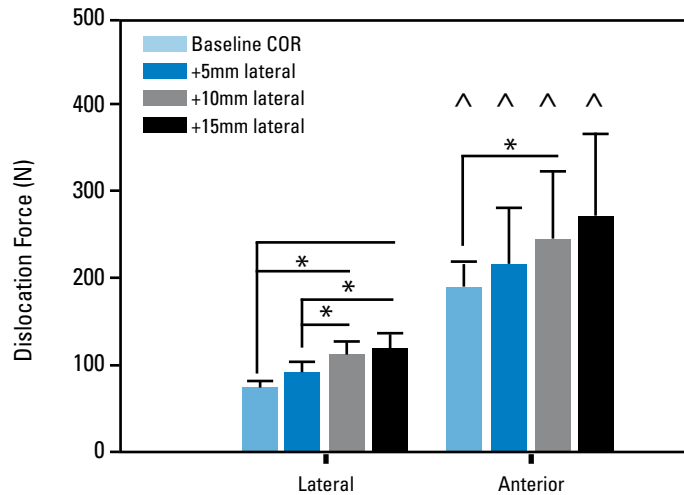


Figure 12

Improved resistance to joint distraction with greater amounts of humeral lateralization¹⁷

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. Male¹

Anatomic Parameter (mm unless noted)	All Humeri	Female	Male	P Value (Male vs Female)
Center of HH to Lesser Tuberosity	25.3 ± 3.5	22.9 ± 2.7	27.8 ± 2.2	<0.0001
Center of HH to Greater Tuberosity	22.4 ± 2.7	21.1 ± 2.5	23.8 ± 2.1	<0.0001
Overall Width	47.7 ± 5.1	43.9 ± 3.4	51.6 ± 3.2	<0.0001

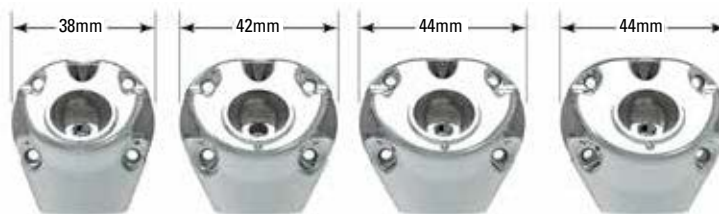


Figure 13

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

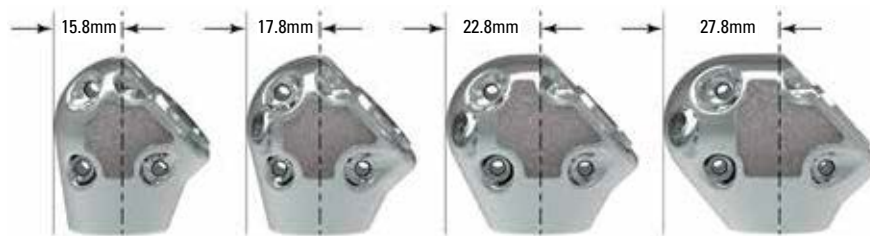


Figure 14

Lateral tuberosity ranges for the four sizes (left to right: small, medium, large and extra large) of proximal bodies utilized in the Equinox Humeral Reconstruction Prosthesis

ROTATIONAL STABILITY

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.¹⁸ 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.²

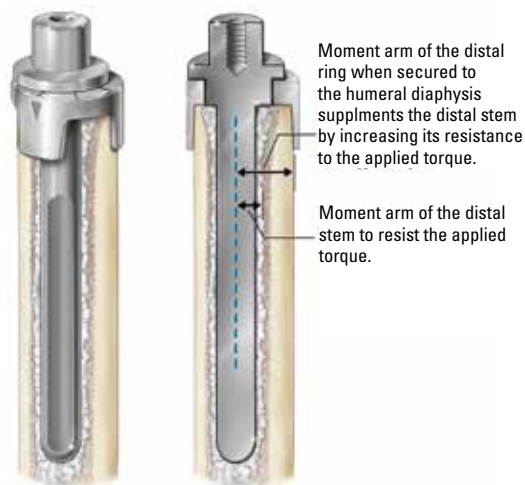


Figure 15

Use of the supplemental diaphyseal collar to improve rotational stability of the distal stem

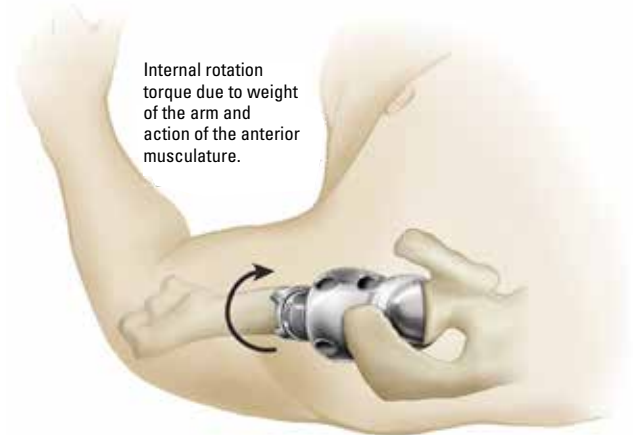


Figure 16

Internal rotation torque during activities of daily living

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 collar²

Sample	Humeral Reconstruction Prosthesis		Cemented Humeral Long Stem	
	Torque to Initiate Slipping (N-m)	Maximum Torque (N-m)	Torque to Initiate Slipping (N-m)	Maximum Torque (N-m)
1	22.6	48.5	14.0	14.0
2	34.3	49.4	5.1	7.0
3	24.2	39.0	11.0	12.5
4	35.7	45.4	5.1	10.4
5	29.4	39.2	5.8	16.6
Average	29.4 ± 5.9	44.3 ± 5.0	8.2 ± 4.1	12.1 ± 3.7
P Value (comparison of stems)	0.0002	<0.0001	0.0002	<0.0001

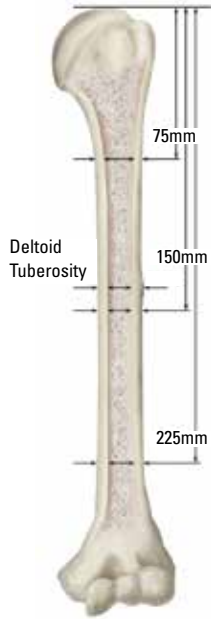


Figure 17

Humeral intramedullary and diaphyseal measurements from the CT scan reconstruction study²³

The distal collar sizing and scope were based upon the results of the CT anatomic reconstruction study of 74 cadaveric shoulders mentioned previously.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.

Table 4: Comparison of Average Humeral Diaphyseal Measurements: Female vs. Male¹

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

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.¹ 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*).

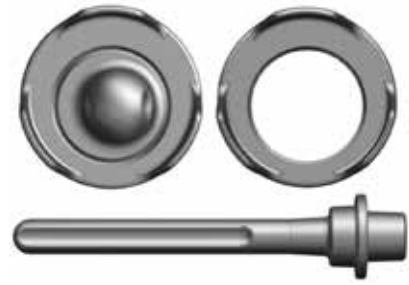


Figure 18
Dual offset tapers of the combined distal stem/collar: Offset distal stem (bottom) and offset diaphyseal collar (right)

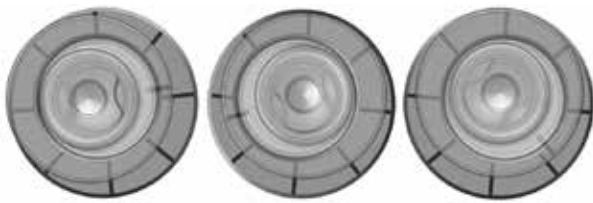
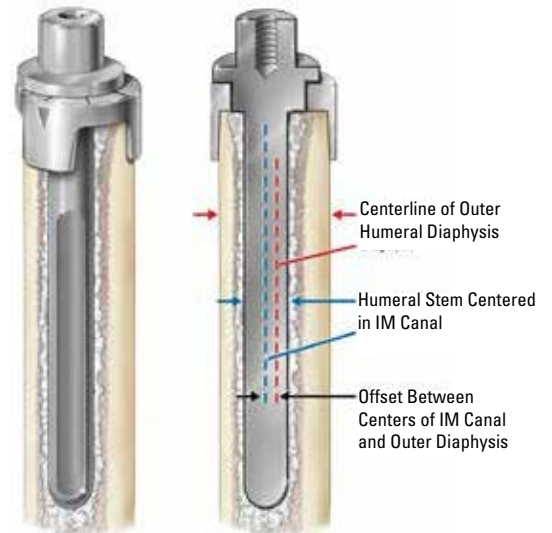


Figure 19
Multiple dual offset combinations of stem and collar



Dual offset of stem and collar necessary to position the humeral stem in the center of IM canal to ensure a uniform cement mantle thickness

Figure 20
Use of the dual offset tapers to center the distal stem within the intramedullary canal and provide a uniform thickness cement mantle while also ensuring the collars fit the humeral diaphysis

METHODS OF SOFT TISSUE REATTACHMENT

The design of the Equinox 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.^{10,19,33,35-49} 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 sutures^{8,19,38,39,44,45,48} 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}



Figure 21
Suture holes and plasma pads to facilitate soft tissue fixation for the 25, 50 and 75mm middle sections

Conclusion



The Equinox 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 Equinox 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*).

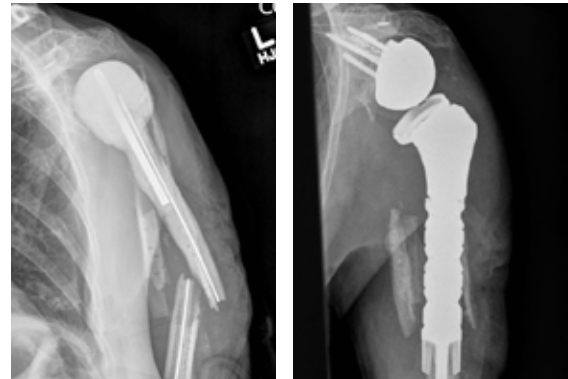


Figure 22
Pre-Operative (Left),
Immediate Post-Operative Radiograph (Right)

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*).



Figure 23
Pre-Operative (Left),
Immediate Post-Operative Radiograph (Right)

CASE 3

This patient had a proximal humerus fracture and was treated with an Equinox 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*).

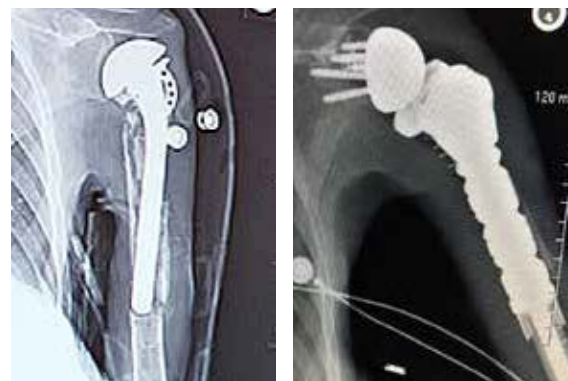


Figure 24
Pre-Operative (Left),
Immediate Post-Operative Radiograph (Right)

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