

Clinical Need for Anatomic Shoulder Replacement, Capable for All Shoulders Coming to Replacement

We believe that for all shoulder conditions coming to replacement, our novel method of glenoid fixation will soon render the non-anatomic Reverse designs obsolete. This claim is important and bears discussion because Reverse designs are preferred for most shoulder replacements today. Our claim is based on the high level in strength of fixation of our novel glenoid implant, one that is reliable and sufficient to withstand the large forces exerted in the early postop period. In addition, this fixation can be sustained without exceeding the limits of micromotion an implant can experience on the bone, for ingrowth of bone and permanent fixation. By this fixation, the glenoid can provide constraint to the humeral head. Hence, anatomic designs are now possible as deemed impossible in prior attempts.

The improved fixation we describe is created without large penetrations using posts or screws. This is advantageous, because destruction of important bone beneath the implant impairs rapid and broad attachment to the bone by bone ingrowth. The Reverse replacements have achieved glenoid implant bone ingrowth by use of aggressive approaches to fixation, rendering their success of ingrowth nearly as reliable as at other sites of joint replacement. At the hip, ingrowth is routine because the prosthetic cup is embedded within a bony socket where it is contained mechanically, to move little even as patients pursue accelerated rehab. Ingrowth occurs reliably into these porous coated metal cups today with fixation that is permanent and dynamic, strengthening under stress as do natural joints.

Our approach to improvement of glenoid fixation can be likened to creation of containing forces that hold the hip cup prosthesis. The forces that contain our glenoid cover implant have high leverage, delivered by extension arms anchored to attachment sites on the scapula. These forces not only contain the cover but eliminate the need for central pegs and screws. Central fixation posts are susceptible to wobble, in engineering terms, causing tipping of the entire implant with high forces and motion in shear at the glenoid cover portion of the implant. In addition, those penetrations reduce the surface area of bone available for ingrowth.

The glenoid region of the scapula presents no more than a precarious perch for a cover implant, but an equal challenge comes from the disturbed mechanics of diseased shoulders with poor rotator cuff function, which will be discussed later. Failure of glenoid fixation can be catastrophic, by dislodgement from the ideal positioning achieved in surgery, or it can come about progressively. Cementing, used for decades, was not found to improve implant fixation over time. Cementless implantation for anatomic-shaped glenoid covers also has limited success. The area is not only small but the head lacks centering guidance, so that rocking of the covering implant often occurs.

Our implant's anchorages to bone employ a unique interference fit, relying on a press-and-lock mechanism without screws. Our work with implant prototypes reveals that fixation is so strong in the presence of good bone that screws into the glenoid can be avoided. Our implants locking in place is created by its method of insertion. The surgical approach is the same as for all replacements today.

We've been advised by experienced regulators in the US, and contract manufacturers who produce many leading company's shoulder implants, that our implant should be brought to market initially for cases with inadequate glenoid bone remaining. It has an obvious advantage for these cases, perhaps sufficient to be a breakthrough product. The condition of lack of glenoid bone occurs after failure of a prior glenoid prosthetic implant and less commonly by failure of development (genetic deformity) or prior trauma, either acute or recurring in sports. Hence, we are developing our glenoid fixation strategy first as an implant that can be used as a replacement for the glenoid module, one that compliments existing shoulder replacement systems now made by leading manufacturers. Eventually we anticipate that recognition of the benefits of stronger glenoid fixation will foster investment in the development of an entirely new shoulder system based around this fixation method, one that can provide an anatomic shoulder replacement well-suited to all cases coming to replacement.

There is much to be learned by history in surgery, and we should heed the clinical failures of shoulder replacements in response to the high forces exerted on the glenoid. These high forces requiring restraint can be observed at the end of a long object by anyone attempting to raise a tall ladder themselves or a broom by its tip. The failure of glenoid implants to resist these high forces led to progressive loosening of the glenoid implant that remains its leading cause of failure. Precise resistance of these forces is more difficult when glenoid bone or cuff function is lacking. For decades prior to the Reverse, the durability of shoulder replacements was linked to a design called 'semi-constrained', in which play between the humerus and scapular implants was permitted, protecting glenoid implant fixation.

The appearance of the Reverse shoulder two decades ago addressed an unmet need that continues. Patients with advanced shoulder disease have varying degrees of cuff dysfunction that cannot be measured today, except with crude clinical assessments and predicted from static images. In many, anatomically designed glenoid replacements failed to restore shoulder function and declines came by glenoid loosening. Anatomic glenoid implants designed to restrain the abnormal motion of the humerus head on the glenoid only accelerated the loosening of these weakly-fixed glenoid implants (DANA shoulder, others). The Reverse presented a reliable solution. Long story short, forces at the shoulder that were pulling constrained anatomic glenoid implants off the underlying bone were converted to compressive forces which stabilized the baseplate of the Reverse. Aggressive fixation of the baseplate fostered ingrowth fixation. Although not anatomic in their shoulder mechanics, the Reverse evolved into a reliable device for pain relief and durability by bone ingrowth.

If the Reverse shoulder has now become so successful to be preferred by most surgeons today, why change? Because it is a consistent rule that surgical remedies which do not mimic nature are eventually overcome by those that do. An anatomic shoulder design capable of ingrowth fixation for all shoulders having arthritis, poor rotator cuff function, and even glenoid bone deficiency can avoid the pitfalls of the Reverse. This new design can provide lower rates of dislocation, better use of the arm and even rehab to high functioning with less trauma leaving more surgical options for reoperation, in the event of complications such as infection. Because this new device resembles more a resurfacing with less foreign material than the Reverse, additional benefits are anticipated.