Shoulder Alignment Obtained with the *Signature* Glenoid Guide System: A Cadaver Study

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Introduction

Proper anatomical alignment of total shoulder prostheses, particularly the glenoid component, is essential to maximize clinical outcomes and achieve long-term success.[1-6] Standard instrumentation can limit the precision of glenoid component placement.[4] As such, the Signature Personalized Patient Care System – Glenoid Guide System (Biomet Inc., Warsaw, IN) has been developed to produce patient-specific positioning guides (PSPGs) that help the surgeon obtain reproducible, anatomical alignment. It is used in conjunction with the anatomic or reverse configurations of the *Comprehensive* shoulder (Biomet, Inc., Warsaw, IN). Briefly, the patient undergoes a pre-operative shoulder CT scan to create a 3-dimensional dataset. This information is used to create a preliminary surgical plan that can be modified by surgeon input. The information contained in the final plan is used to direct the fabrication of a single-use PSPG via additive manufacturing. The PSPG consists of a base portion that reproduces the patient's glenoid and from which two straight guides extend, corresponding to use with the anatomic and reverse shoulder configurations, respectively (see Figure 1). Following appropriate removal of soft tissue from the glenoid, the PSPG is placed onto the glenoid where it fits with close registry. The guide appropriate to the shoulder configuration being implanted (anatomic or reverse) is used to direct a pin into the glenoid. The PSPG is then removed leaving the pin in place. Cannulated instrumentation used over the guide pin prepares the glenoid to accept the central peg of the prosthetic glenoid (anatomical configuration) or the central screw for the glenoid baseplate (reverse configuration). The purpose of this study was to examine the alignment achieved using the Signature system.

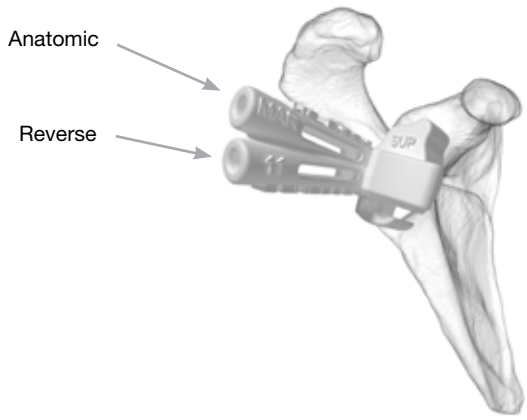

Fig. 1
Signature Glenoid Guide in position on glenoid with the locations for the guide pins for the anatomic and reverse configurations of the Comprehensive shoulder identified.

Materials and Methods

A total of 12 scapula to finger tip cadaver specimens were obtained. These were divided into 4 subgroups of 3 specimens each, i.e., Group 1) anatomic configuration receiving only pins, Group 2) anatomic configuration receiving implants, Group 3) reverse configuration receiving only pins, and Group 4) reverse configuration receiving implants. Pins-only were used for convenience in some groups because they were radiopaque and could be used as well as actual implants to measure alignment.

Four surgeons highly experienced in total shoulder arthroplasty performed the procedures. Following surgery, CT scans were taken of the shoulders and the version and inclination of the implanted hardware was determined through software analysis. Also, the insertion point of the guide pin was measured as well and compared with the Signature surgical plan.

Table 1. Summary of shoulder alignment data					
Group	Configuration	Hardware	Version (°)*	Inclination (°)*	Offset (mm)
1	Anatomic	Pin	-0.6	-1.0	0.4
			-1.7	0.6	0.3
			-3.8	-4.1	0.9
2		Implant	-6.2	-2.9	0.4
			-4.9	-4.5	2.4
			2.5	2.3	2.5
3	Reverse	Pin	-6.5	5.8	1.5
			5.4	1.8	1.4
			-1.0	3.6	1.7
4		Implant	0.3	0.7	2.2
			-4.8	4.2	1.7
			2.0	4.3	1.5
Mean ± SD			-1.6 ± 3.8°	0.9 ± 3.4°	1.4±0.8 mm

*Note: negative reflects retroversion and inferior tilt, positive reflects anteversion and superior tilt

Results

The Table summarizes alignment of the individual shoulders. Clinical and biomechanical studies have suggested, based on wear, loosening, stability, and impingement considerations, acceptable deviations from neutrality for glenoid component position are ±10° for version and inclination and 4 mm in three-dimensional space from the center of the glenoid (offset).[3-8] As can be seen, each shoulder attained acceptable alignment with no outliers.

Discussion/Conclusion

The Signature system seeks to establish a neutrally positioned glenoid component, although as mentioned above, the surgeon can modify the preliminary plan as he/she deems necessary for the unique requirements of a given patient. As such, the acceptable deviations from the final Signature plan are ±10° for version and inclination and 4 mm for offset. In the current study, all twelve shoulders (six anatomical and six reverse configurations) were within these limits with no outliers. Iannotti, *et al.*[5], examined retroversion in 13 patients receiving a standard, multi-pegged glenoid component. They considered ideal version to be that which was as close to perpendicular to the plane of the scapula, with complete contact of the back side of the component on glenoid bone and maintenance of the center peg of the component within bone. As such, ideal component retroversion was not zero in all cases, but ranged from 2° to 17° for shoulders with a preoperative retroversion of 19-42°. Three of the 13 shoulders (23%) had actual component retroversion that deviated more than 10° from the ideal value. These three outliers had preoperative retroversion of 10°, or greater. In cases with less than 10° of preoperative retroversion, the glenoid component was placed within 10° of ideal version in all cases. Hendel, *et al.* (4), performed a randomized, controlled study of glenoid placement with a PSPG system (n=15) vs. use of conventional instrumentation (n=16). The incidence of implant malposition in version and/or inclination for these two groups was 27% and 75%, respectively ($p<0.01$). The greatest benefit of the PSPGs was observed in patients with preoperative retroversion in excess of 16°, with the average deviation being 10° in the conventional group and 1.2° in the PSPG group ($p<0.001$). Suero, *et al.*[1], examined glenoid positioning among a cohort of three conventional and four reverse shoulders using a PSPG system, finding deviations from plan of 0.2±8.2° more superior inclination, 3.4±7.2° more retroversion, and 3.4±1 mm of translational deviation, similar to the results of the current study.

Although the use of PSPGs for shoulder replacement surgery is a relatively new development, the preliminary data presented in the current study, as well as published data, suggest its suitability for addressing glenoid component alignment.[1-8] Additional studies of the Signature system in the context of total shoulder replacement will be required to more fully evaluate the potential of this technology.

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