

Curvafix® IM Implant

Pelvic Morphology

The CurvaFix IM implant is a revolutionary curved implant for the fixation of pelvic ring and acetabular injuries. The flexible device is implanted through a small incision over a steerable guidewire into the intramedullary space (center of the bone) and then locked into a rigid state to stabilize and repair a fracture.

The intramedullary fixation paths for the CurvaFix IM implant are larger in diameter and length than the paths available for straight, cannulated screws. In many dysmorphic sacra, there are acceptable curved iliosacral paths for the CurvaFix Implant. Paths for straight screws are rarely available in the upper (S1) part of a dysmorphic sacrum.

Potential safe curved intramedullary fixation paths (CIFPs) in the pelvic ring were analyzed using computed

tomography (CT) scans of 101 intact pelvis (50:51 male:female). The minimum diameters (constriction points), radii of curvature (RoC), and potential lengths of these CIFPs were assessed. A high proportion of patients had a CIFP ≥ 10 mm and a RoC > 65 mm, illustrating that the CurvaFix IM implant could be safely introduced into the pelvic rings of much of the population.

Potential eligible population based on CIFP minimum diameters - mm

		PROPORTION OF PATHS IN MEASURED POPULATION			MEAN	+/- SD	RANGE
		Male	Female	All			
Anterior column, pubic rami path*	≥ 10 mm	98%	76%	87%	13	± 3	7 to 21
Anterior column, supra-acetabular**	≥ 10 mm	98%	80%	89%	12	± 3	7 to 18
Posterior column	≥ 10 mm	100%	100%	100%	19	± 3	15 to 24
Iliosacral, across S1 [†]	≥ 10 mm	98%	96%	97%	17	± 3.5	8 to 23

*The smaller diameters of the pubic ramus correlate with height and females who are ~ 5 feet tall or less should be more carefully evaluated for implant fit

**Some patients have protrusion acetabulae which narrows the space above the acetabulum

[†]A few patients with dysmorphism did not have adequate size on one side or the other. The majority, had adequate (more than 10mm) on both sides.

Radii of curvature (RoC) - mm

	PROPORTION OF POPULATION > 65 MM
Anterior column	95%
Iliosacral tunnel	100% [†]

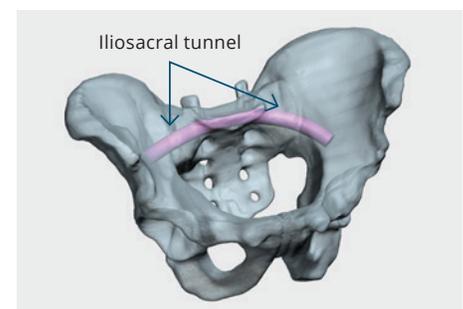
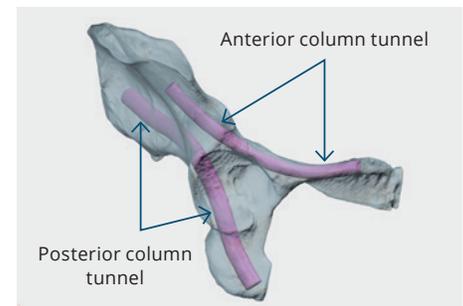
Potential curved intramedullary fixation path (CIFP) lengths - mm

	MEAN	+/- SD	RANGE
Anterior column, posterolateral approach	137	± 9	112 to 159
Anterior column, anterior approach	131	± 9	108 to 154
Iliosacral, inlet view, short path	142	± 10	123 to 163
Iliosacral, inlet view, long path	180	± 14	152 to 215
Iliosacral, outlet view, short path	135	± 7	123 to 149
Iliosacral, outlet view, long path	159	± 8	143 to 174
Trans pubic symphysis	214	± 14	178 to 242

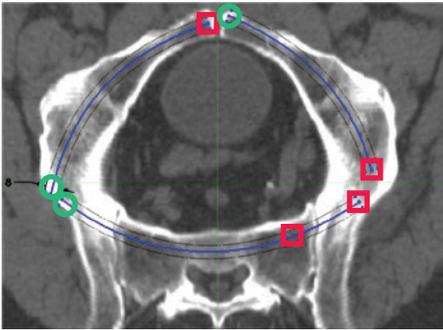
Long path - ilium to ilium

Short path - ilium to just short of the contralateral sacroiliac joint

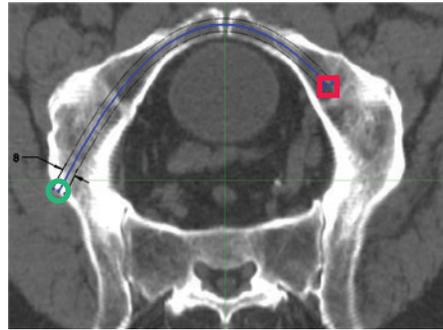
[†]96% of iliosacral tunnels had a RoC > 110 mm



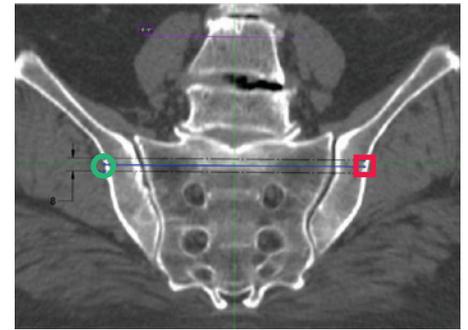
Curved intramedullary fixation paths (CIFPs) in normal sacra – starting point in green, terminus in red



Inlet view. Posterolateral and anterior approaches to the anterior column. The two red squares on the iliosacral CIFP indicate the terminus of the short and long paths.



Inlet view. CIFP across the pubic symphysis.



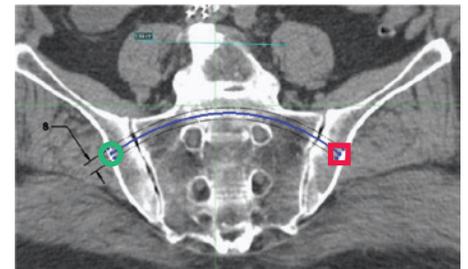
Outlet view. The CIFP can appear straight (convex superior) in this view.

Sacral Dymorphism

Forty two percent of the cases studied had some form of sacral dymorphism. Posterior iliosacral fixation tunnels were measured at the narrowest canal of the sacral ala.

In dymorphic sacra, constriction points on the straighter S2 path for all but one patient were ≥ 10 mm and were larger than in normal sacra. Four dymorphic sacra had S1 constriction points < 10 mm but with ≥ 10 mm along S2.

In the dymorphic pelves, the inferior to superior curvature made it impossible to make a straight tunnel from ilium to ilium but a curved tunnel was possible in all cases.



Outlet view. An iliosacral CIFP in a dymorphic sacrum. In this case (and approximately half of the dymorphic cases), the best fit curve is convex anterior, which is different from the curve in normal sacra in this view.

Methods

Population: 101 pelvic CT scans (50 male, 51 female) acquired for the diagnosis and treatment of soft tissue tumors in the pelvic area were analyzed. The study population height and weight were representative of the US population.

Curved intramedullary fixation path constriction points and lengths:

MIM Maestro software was used to create views similar to those used in the operating room (with an image intensifier) to place cannulated screws: inlet and outlet views of the pelvic ring and tangential views of the anterior and posterior columns of the acetabulum. MIM Maestro's 3D spherical contouring tool was used to measure constriction points. The posterior column has gentler curves in its medullary canal and wider

constriction points than the anterior column and therefore 18 (9 male, 9 female) randomly selected scans were evaluated. Spheres were placed in the constriction points and expanded to tangentially touch the inner surface of the cortical bone. The sphere was then checked in all three orthogonal views to verify it was within the cortical wall. For each anterior column, additional spheres were placed 10 mm lateral and medial to the first to confirm the constriction point. In the iliosacral region, the narrowest thickness on both sides of the sacral ala was determined to avoid the S1 foramen, the L5-S1 disc space, and the upper ala of the sacrum where the L5 nerve root is closely applied to the bone. Constriction points in S1 and S2 were checked in both inlet and outlet views of the sacrum. Curved intramedullary fixation path

lengths were determined using MIM Maestro.

Radii of curvature: A transparent overlay with a scale line and a 65-mm radius reference circle with a circumference 11-mm in width (representing an 11-mm canal) was prepared. The scale line on the overlay and the case screen image were aligned and then the overlay was moved over the screen image to determine if radius of the bone was inside or outside the reference circles. The method was repeated for a 110-mm radius circle with a 12.5-mm canal.

This method was described in Zakariaee et al. A Feasibility Study of Pelvic Morphology for Curved Implants. *Injury* 2016;47:2195-2202.

Disclaimer: For Reference Only. Please refer to the Instructions for Use (IFU) for complete listing of indications, contraindications, warnings, and directions for use. The CurvaFix IM Implant is 510(k) cleared by the FDA and intended for fixation of fractures of the pelvis. Statements and information contained herein have not been evaluated by the Food and Drug Administration.

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