

CurvaFix[®] IM Implant

Implant Removal in an Ovine Model



Introduction

The CurvaFix IM Implant is a revolutionary curved implant for the fixation of pelvic fractures. The flexible device is implanted through a small incision over a steerable guidewire into the intramedullary space and then locked, converting it into a rigid state, to stabilize and repair a bone fracture. If explantation is required, the CurvaFix IM Implant is designed to be unlocked, returning the implant to a flexible state, and then removed by rotating the implant counterclockwise.

An ovine model was used to determine ease of implant removal from intact ovine pelvis at ≥ 9 weeks post implantation by unlocking and then rotating the implant. Previous studies on a harvested sheep pelvis indicated the implant could successfully follow the path from the iliac crest, superior to the acetabulum, and into the anterior column. The path is curved and allows separation of the segments of the implant along its length. After implantation, gaps between the segments allow for potential bone in-growth.

Methods

Four healthy sheep (72-89 kg) were implanted with CurvaFix IM Implants and were survived at least 65 days (9.3 weeks). One additional sheep received an implant on the right side but was sacrificed early at 7 days due to mobility issues secondary to an iliac wing fracture (discovered post sacrifice), which likely occurred during experimental reaming on the left side in an unexpectedly narrow intramedullary canal. Sheep were prepared for surgery per standard procedures. A small incision was made over the iliac crest and dissected to the bone. The clinical procedure for CurvaFix IM Implant implantation was followed. The surgical wound was closed with suture and the procedure was repeated on the contralateral iliac crest. After recovery, the sheep were returned to the paddock and monitored for overall health and mobility. For explantation, an incision was made at the scar and dissected down to the head of the implant. The torque required to unlock the implant was measured by torque meter. The implant was loosened within the bone by a series of clockwise and counterclockwise turns and after a complete 360° counterclockwise turn, the implant was removed, and the maximum torque required to remove the implant was recorded.



Representative example of CurvaFix IM Implants in the iliac crest gluteal pillars of an ovine model (bilateral).

Explantation Results

No.	Side	Survival (days)	Unlock torque (Nm)	Removal torque (Nm)	Implant removed by rotation
1	L	85	2.2	2.5	Yes
	R		2.5	N/A ^a	No ^a
2	L	84	2.2	3.1	Yes
	R		1.5	6.0	Yes
3	L	85	1.6	4.1	Yes
	R		1.7	0.0	Yes
4	L	65 ^b	N/A ^c	N/A ^c	N/A ^c
	R		1.5	2.1	Yes
Mean \pm standard deviation			1.7 \pm 0.4	3.0 \pm 2.0	

- Distal threaded segment was placed in a narrow region of the intramedullary canal immediately adjacent to cortical bone, resulting in cortical in-growth between threads of the distal segment. This may have prevented the threaded segment from loosening by rotation with the method used. All other segments along the length of the implant rotated with minimal applied torque. This implant was flexible immediately upon removal.
- Sacrificed early due to weight bearing issues (right) secondary to a fracture superior/partially into the acetabulum, likely the result of a fall.
- Left side implant was not successfully implanted and therefore, removal could not be evaluated.

Conclusion

Bony in-growth into the CurvaFix IM Implant at 65-85 days (9-12 weeks) post implantation was unremarkable, as evidenced by the low torque required to unlock and remove by rotation in 6 of 7 implants. All implants successfully converted from rigid to flexible state upon unlocking. Conversion to flexible state was evaluated immediately upon removal. Explantation of the CurvaFix IM Implant is feasible 9-12 weeks post implantation.