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ABOUT COVER

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ORIGINAL ARTICLE

Basic Study

Sacroiliac joint stability: Finite element analysis of implant number, orientation, and superior implant length

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Abstract

AIM

To analyze how various implants placement variables affect sacroiliac (SI) joint range of motion.

METHODS

An experimentally validated finite element model of the lumbar spine and pelvis was used to simulate a fusion of the SI joint using various placement configurations of triangular implants (iFuse Implant System®). Placement configurations were varied by changing implant orientation, superior implant length, and number of implants. The range of motion of the SI joint was calculated using a constant moment of 10 N-m with a follower load of 400 N. The changes in motion were compared between the treatment groups to assess how the different variables affected the overall motion of the SI joint.

RESULTS

Transarticular placement of 3 implants with superior implants that end in the middle of the sacrum resulted in the greatest reduction in range of motion (flexion/extension = 73%, lateral bending = 42%, axial rotation = 72%). The range of motions of the SI joints were reduced with use of transarticular orientation (9%-18%) when compared with an inline orientation. The use of a superior implant that ended mid-sacrum resulted in median reductions of (8%-14%) when compared with a superior implant that ended in the middle of the ala. Reducing the number of implants, resulted in increased SI joint range of motions for the 1 and 2 implant models of 29%-133% and 2%-39%, respectively,

when compared with the 3 implant model.

CONCLUSION

Using a validated finite element model we demonstrated that placement of 3 implants across the SI joint using a transarticular orientation with superior implant reaching the sacral midline resulted in the most stable construct. Additional clinical studies may be required to confirm these results.

Key words: Fusion; Biomechanics; Minimally invasive surgery; Sacroiliac joint dysfunction; Finite element analysis

Core tip: Minimally invasive fusion of the sacroiliac (SI) joint is a potential treatment for patients suffering with symptoms related to the SI joint. This study used finite element analysis to investigate how implant orientation, superior implant length, and implant number affect SI joint range of motion. The results of this study demonstrate that placement of 3 implants across the SI joint using a transarticular orientation with superior implant reaching the sacral midline resulted in the most stable construct.

Lindsey DP, Kiapour A, Yerby SA, Goel VK. Sacroiliac joint stability: Finite element analysis of implant number, orientation and superior implant length. *World J Orthop* 2018; 9(3): 14-23 Available from: URL: http://www.wjgnet.com/2218-5836/full/v9/i3/14.htm DOI: http://dx.doi.org/10.5312/wjo.v9.i3.14

INTRODUCTION

Minimally invasive fusion of the sacroiliac (SI) joint is a potential treatment for patients suffering with symptoms related to the SI joint. Although diagnosis of the primary pain generator in low back pain is challenging[1], proper diagnosis allows for the most effective treatment. Of patients dealing with low back pain, between 15% and 30% have the SI joint as a pain generator[2-4].

Recently, minimally invasive fusion of the SI joint has been shown to be an effective method for reducing SI joint pain[5]. In addition, minimally invasive procedures have been shown to reduce blood loss, length of stay, and surgical time, while resulting in more positive outcomes for the patient compared with traditional open fusion procedures[5].

There are many factors that influence the choice and placement of implants placed across the SI joint. The sacral anatomy allows for placement of iliosacral hardware within sacral safe zones, although differences in anatomy have a significant effect on the location and size of the safe zones[6]. There is evidence that placement of multiple implants in unstable pelvic fracture models results in the greatest biomechanical stability[7-9]. Additional studies have demonstrated that placement of iliosacral screws within regions of higher bone density result in higher extraction forces[10,11].

Previous *ex vivo* experimental studies have investigated the biomechanical effects of placing SI joint fusion devices[12,13]. These studies have shown that placement of 3 triangular titanium plasma spray (TPS) coated titanium implants significantly reduced motion of the treated SI joint. A comparison of two lateral placement variations, inline (posterior) and transarticular, showed that both variations significantly reduced motion, and suggested that the transarticular orientation may provide more initial stability.

Finite element modeling is another technique used to investigate the biomechanics of the SI joint and pelvis[14-17]. Ivanov *et al*[14,15] validated an SI joint FE model by comparing the FEA model ROM with experimental data for the intact and sequential ligament sectioning conditions from Simonian *et al*[18]. This SI joint model was later confirmed[17] to demonstrate that SI joint treatment using implants resulted in comparable reductions in motion to those reported in cadavers by Soriano-Baron *et al*[13].

Although, clinical and experimental evidence shows that placing 3 triangular TPS coated implants has successful clinical and biomechanical results, questions remain concerning the optimal parameters for implant placement. The objective of this study was to investigate and quantify the effect of implant orientation, superior implant length, and implant number on SI joint range of motion.

MATERIALS AND METHODS

A finite element model of the lumbar spine, pelvis, and both femurs was used to simulate SI joint motion; this model has previously been used to evaluate the effects of leg length discrepancy, effects of lumbar spine fusion on the SI joint, and effects of SI joint fusion on the lumbar spine[14-17]. The femoral head was fixed into the acetabular cup to ensure loading, but that no motion occurred at the hip joint. Briefly, a pelvis was scanned using computed tomography (CT) and material properties for bones, ligaments, and joints were assigned[14,15]. The material properties of the sacral cancellous bone were assumed to be isotropic and varied in accordance to the apparent bone mineral density from a normal sacrum (t-score > -1)[19] using a power law distribution ($\alpha = 2$)[20]. For treated models, the core of the titanium plasma spray (TPS) coated implants (iFuse Implant 7.0 mm; SI-BONE, Inc., San Jose, CA, United States) was assigned the material properties of Ti6Al4V ELI (E = 115 GPa), the interface between the implant core and adjacent bone can be found in Lindsey *et al*[17].

Loading conditions/outcomes

The intact and instrumented model loads were simulated using a compressive follower load of 400 N,

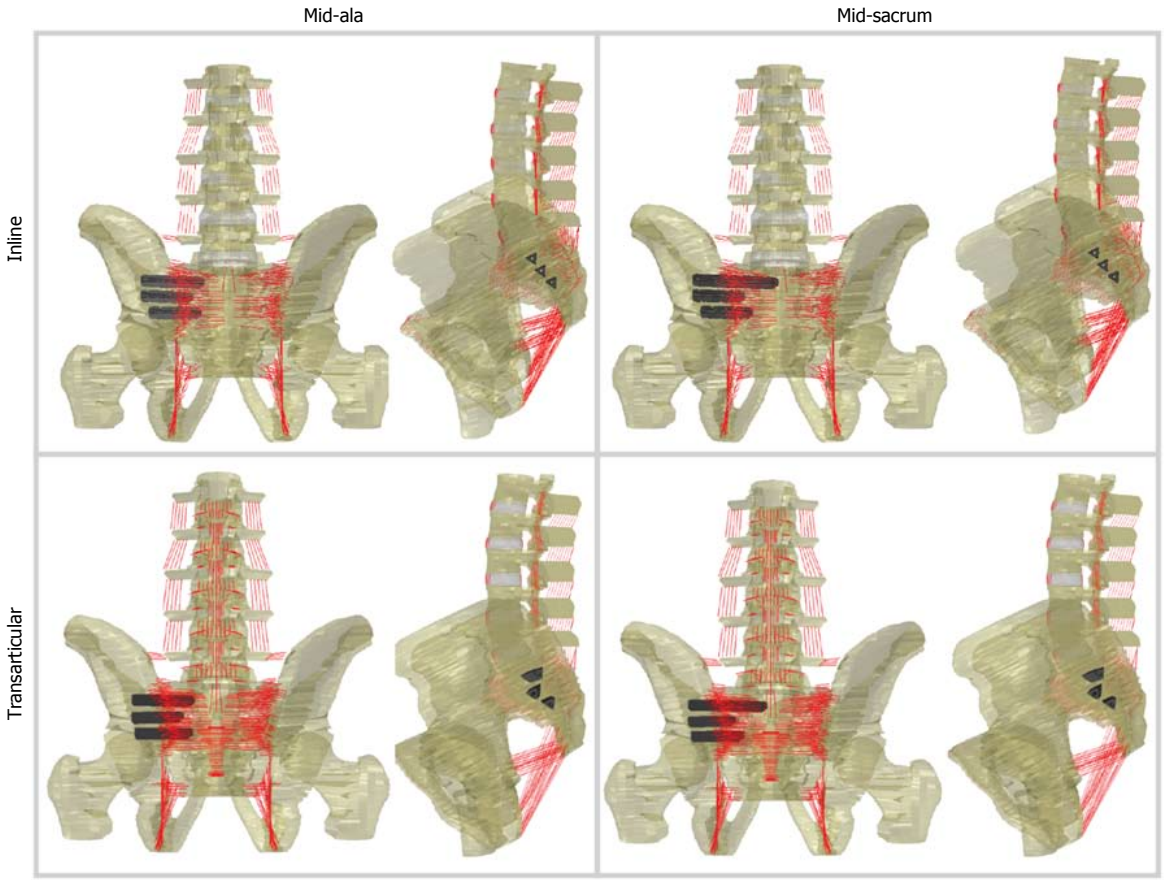

Figure 1 Finite element models tested in this study used either an inline or transarticular orientation. For models that included a superior implant, the length was varied such that the implant ended above the S1 foramen (mid-ala) or the midline of the sacrum (mid-sacrum).

and a 10 N-m bending moment applied at the superior surface of the L1 vertebra[21,22]. The compressive follower load was extended to the sacrum level and the angle of the connector elements defined such that the entire lumbo-pelvic segment did not go into any rotational motion following contraction of the connector elements. Loading was simulated in flexion-extension, lateral bending (left and right), and axial rotation (left and right) during double-leg stance. The range of motion of the SI joint was determined for each loading direction[14].

Treatment groups

Three treatment variables were investigated: Implant orientation, superior implant length, and implant number. Two potential implant orientations, inline (posterior) and transarticular, have been previously investigated[13] and both were further investigated here (Figure 1). Clinically, the superior implant length is often chosen to end within the middle of the ala (*i.e.,* directly above the S1 foramen); based upon previous trauma literature[11], we also investigated a longer superior implant that extended to the midline of the sacrum (Figure 1). Typically, three implants are placed[23], for this investigation either 1, 2, or 3 implants were placed. All potential instrumented combinations were simulated, resulting in 22 unique models (Table 1). The superior implant was either 55 mm long (mid-ala) or 75 mm long (mid-sacrum) for both the inline and transarticular orientation (placement of the superior implant is identical for the two orientations). The middle implants were 45 mm long for both the inline and transarticular orientations, while the inferior implant was 45 mm long for the inline orientation and 50 mm long for the transarticular orientation.

Statistical analysis

The effect of treatment was assessed by calculating the difference in ROM between the intact and treated configurations for each combination of implant orientation, superior implant length, and number of implants in flexion-extension, lateral bending, and axial rotation. The percent change was calculated in comparison with the intact ROM. The median and range for the difference in ROM and percent change were determined for each motion. Effects of individual treatment variables are described below.

Implant orientation: The effect of implant orientation was assessed by calculating the difference between the inline and transarticular (TA) configurations. Differences in ROM were calculated as a function of superior implant length (SIL) (mid-ala, mid-sacrum, or none) and number of implants (3-superior/middle/inferior, 2-

Table 1 Sacroiliac joint range of motion for an intact model and 22 configurations of implant orientation, superior implant length, and number of implants

Treatment/orientation	Implant placed			Superior implant ending point	SI joint ROM (°) [Reduction in ROM (%)]		
	Superior	Middle	Inferior		Flexion-extension	Lateral bending	Axial rotation
Intact	-	-	-	-[1]	1.94° (-)	0.66° (-)	1.11° (-)
Inline orientation	X	X	X	Mid-ala	0.7° (64%)	0.45° (32%)	0.41° (63%)
				Mid-sacrum	0.63° (68%)	0.41° (38%)	0.38° (66%)
	X	-	X	Mid-ala	0.82° (58%)	0.47° (29%)	0.44° (60%)
				Mid-sacrum	0.69° (64%)	0.43° (35%)	0.4° (64%)
	X	X	-	Mid-ala	0.97° (50%)	0.5° (24%)	0.49° (56%)
				Mid-sacrum	0.76° (61%)	0.45° (32%)	0.43° (61%)
	-	X	X	-[1]	0.91° (53%)	0.53° (20%)	0.55° (50%)
	X	-	-	Mid-ala	1.36° (30%)	0.58° (12%)	0.67° (40%)
				Mid-sacrum	1.21° (38%)	0.58° (12%)	0.61° (45%)
	-	X	-	-[1]	1.32° (32%)	0.65° (2%)	0.73° (34%)
	-	-	X	-[1]	1.25° (36%)	0.69° (-5%)	0.79° (29%)
Transarticular orientation	X	X	X	Mid-ala	0.59° (70%)	0.41° (38%)	0.34° (69%)
				Mid-sacrum	0.52° (73%)	0.38° (42%)	0.31° (72%)
	X	-	X	Mid-ala	0.69° (64%)	0.42° (36%)	0.36° (68%)
				Mid-sacrum	0.58° (70%)	0.39° (41%)	0.32° (71%)
	X	X	-	Mid-ala	0.81° (58%)	0.45° (32%)	0.4° (64%)
				Mid-sacrum	0.64° (67%)	0.41° (38%)	0.35° (68%)
	-	X	X	-[1]	0.76° (61%)	0.47° (29%)	0.46° (59%)
	X	-	-	Mid-ala	1.36° (30%)	0.58° (12%)	0.67° (40%)
				Mid-sacrum	1.21° (38%)	0.58° (12%)	0.61° (45%)
	-	X	-	-[1]	1.11° (43%)	0.6° (9%)	0.7° (37%)
	-	-	X	-[1]	1.05° (46%)	0.62° (6%)	0.73° (34%)

[1]Configuration does not include a superior implant. SI: Sacroiliac; ROM: Range of motion.

superior/inferior, 2-superior/middle, 2-middle/inferior, 1-middle, and 1-inferior), for a total of 9 combinations. The percent change was calculated in comparison with the inline ROM. The treatment of one implant in the superior position was not compared between orientations since the configurations are identical for the inline and transarticular orientations. The median and range for the difference in ROM and percent change were determined.

Superior implant length: The effect of the superior implant length was assessed by calculating the difference between the mid-sacrum (MS) and mid-ala (MA) configurations. Differences in ROM were calculated as a function of orientation (Inline, Transarticular) and number of implants (3-superior/middle/inferior, 2-superior/inferior, 2-superior/middle, and 1-superior), for a total of 8 combinations. The percent change was calculated in comparison with the ROM of mid-ala superior implant length. The median and range for the difference in ROM and percent change were determined.

Implant number: The effect of implant number was assessed by calculating the difference in ROM between all single or dual implant configurations and the corresponding 3 implant configuration as a function of orientation (Inline, Transarticular) and superior implant length (SIL) (mid-ala, mid-sacrum) for a total of 18 combinations, and normalizing by the corresponding 3 implant configuration (implants without a superior implant were normalized to the mid-ala configuration). The median and range for the difference in ROM and percent change were determined for each single or dual implant configuration.

Animal care and use statement

The article does not contain any studies with human participants or animals performed by any of the authors.

RESULTS

Placement of 3 implants using the inline and transarticular orientations resulted in reductions in motion of 64%, 32%, 63%, and 70%, 38%, 69%, in flexion-extension, lateral bending, and axial rotation, respectively (Table 1). These reductions are consistent with the range of reductions reported by Soriano-Baron *et al*[13] and provided confidence that this FE model is sufficient to make comparisons between treatment variables that have not previously been investigated in cadaver studies (*i.e.*, implant number, placement technique, and superior implant length).

Transarticular placement of 3 implants with a mid-sacrum length superior implant resulted in the greatest reduction in range of motion (Table 1). One superior implant (mid-ala length) has the least reduction in range of motion in flexion-extension; one inferior implant placed using the inline orientation has the least reduction in range of motion in lateral bending and axial rotation. Transarticular placement of a superior (mid-sacrum length) and inferior implant has the most reduction in range of motion for a 2 implant configuration.

Table 2 Reduction in sacroiliac joint range of motion (°) between transarticular and inline orientation groups

Orientation	Implants (positions)	Superior implant ending point	Reduction in SI joint ROM (°) (%)		
			Flexion-extension	Lateral bending	Axial rotation
Transarticular *vs* inline	3 (S, M, I)	Mid-ala	0.11° (16%)	0.04° (9%)	0.07° (17%)
		Mid-sacrum	0.11° (17%)	0.03° (7%)	0.07° (18%)
	2 (S, -, I)	Mid-ala	0.13° (16%)	0.05° (11%)	0.08° (18%)
		Mid-sacrum	0.11° (16%)	0.04° (9%)	0.08° (20%)
	2 (S, M, -)	Mid-ala	0.16° (16%)	0.05° (10%)	0.09° (18%)
		Mid-sacrum	0.12° (16%)	0.04° (9%)	0.08° (19%)
	2 (-, M, I)	-[1]	0.15° (16%)	0.06° (11%)	0.09° (16%)
	1 (-, M, -)	-[1]	0.21° (16%)	0.05° (8%)	0.03° (4%)
	1 (-, -, I)	-[1]	0.20° (16%)	0.07° (10%)	0.06° (8%)
	Median (°) (Range)		**0.13° (0.11-0.21)**	**0.05° (0.03-0.07)**	**0.08° (0.03-0.09)**
	Median (%) (Range)		**16% (16-17)**	**9% (7-11)**	**18% (4-20)**

[1]Configuration does not include a superior implant. S: Superior; M: Middle; I: Inferior.

Altering the implant orientation from the inline to the transarticular placement technique resulted in median reductions in motion of 16%, 9% and 18%, in flexion-extension, lateral bending, and axial rotation, respectively (Table 2).

Extending the superior implant to the midline of the sacrum resulted in median reductions in motion of 14%, 8% and 9%, in flexion-extension, lateral bending, and axial rotation, respectively (Table 3).

The two implant models with superior and inferior implants resulted in increased motions of 10%-17%, 2%-5% and 3%-7% compared with the 3 implant model, in flexion-extension, lateral bending, and axial rotation, respectively (Figure 2). Two implant models configurations with the implants placed close together (superior/middle, and middle/inferior) resulted in increased motions when compared with the 3 implant configuration of 21%-39%, 8%-18%, and 13%-35% in flexion-extension, lateral bending, and axial rotation, respectively (Figure 2; Tables 4-6). For single implant models, the motion increases ranged from 78% to 133%, 29% to 53% and 61% to 115%, in flexion-extension, lateral bending, and axial rotation, respectively (Figure 2).

DISCUSSION

The finite element model used in this study resulted in intact and treated SI joint motions that are consistent with previous experimental studies[13]. The combination of the current results and the previous validations confirm that both the intact and treated models in this study are functioning in a physiologic manner.

The current study demonstrated that the implant orientations across the SI joint can alter the range of motion. The SI joint contains both cartilaginous and fibrocartilaginous portions, with the cartilaginous portion exhibiting greater subchondral sacral bone density[19]. The transarticular orientation positions the middle and inferior implants more ventrally (approximately 15°-20°) and across the cartilaginous portion of the SI joint (Figure 1). Soriano-Baron *et al*[13] reported that the transarticular orientation had larger average reduction in SI joint ROM, although this was not determined to be significant.

The current study also demonstrated that placement of a longer superior implant resulted in reduced SI joint range of motion. Kraemer *et al*[11] demonstrated that iliosacral screws had a higher pullout force when the threads were positioned in the sacral midbody compared with those positioned in the ala. The results from Kraemer *et al*[11] are consistent with later anatomical studies that have reported reduced bone mineral density within the ala[24]. The current study demonstrated that increasing the length of the superior implant to the higher density bone of the sacral midline reduces the range of motion of the SI joint in flexion-extension, lateral bending, and axial rotation. Clinically, anatomic constraints must be considered prior to placement of a longer first implant.

The current study also demonstrated that placement of 3 implants resulted in greater motion reduction than any combination of two implants. Multiple studies have demonstrated that the use of a single SI screw results in less stability when compared with 2 SI screws[7-9]. The current study investigated treatment with 1, 2, or 3 implants to evaluate the treated SI joint range of motion as a function of implant number. Clinically, a prospective randomized trial documented 3 implants being placed in 91% of cases; with the rest of the cases using either 2 implants (5% cases) or 4 implants (4% cases)[23]. Although a small portion of clinical cases used 4 implants, this condition was not investigated in this study as placement is highly dependent on the size of the sacrum. The results from the current study demonstrate that reducing the number of placed implants results in increased initial SI joint range of motion. Two implants with increased separation, however, are more stable than 2 implants placed close together.

The current study is not without limitations. As with all finite element models, certain assumptions must be made to model the system. As previously noted, the current model is based on a single patient and did not

Table 3 Reduction in sacroiliac joint range of motion (°) between mid-sacrum and mid-ala placement groups

Superior implant ending point	Orientation	Implants (position)	Reduction in SI joint ROM (°) (%)		
			Flexion-extension	Lateral bending	Axial rotation
Mid-sacrum *vs* mid-ala	Inline	3 (S, M, I)	0.07° (10%)	0.04° (9%)	0.03° (7%)
		2 (S, -, I)	0.13° (16%)	0.04° (9%)	0.04° (9%)
		2 (S, M, -)	0.21° (22%)	0.05° (10%)	0.06° (12%)
		1 (S, -, -)	0.15° (11%)	0.00° (0%)	0.06° (9%)
	Trans-articular	3 (S, M, I)	0.07° (12%)	0.03° (7%)	0.03° (9%)
		2 (S, -, I)	0.11° (16%)	0.03° (7%)	0.04° (11%)
		2 (S, M, -)	0.17° (21%)	0.04° (9%)	0.05° (13%)
		1 (S, -, -)	0.15° (11%)	0.00° (0%)	0.06° (9%)
	Median (°) (Range)		**0.14° (0.07-0.21)**	**0.035° (0.00-0.05)**	**0.045° (0.03-0.06)**
	Median (%) (Range)		**14% (10-22)**	**8% (0-10)**	**9% (7-13)**

The reduction in range of motion (%) was calculated in comparison to the to the mid-ala superior implant length. S: Superior; M: Middle; I: Inferior.

Table 4 Change in sacroiliac joint flexion-extension range of motion (°) as a result of reducing the number of implants

Treatment	Implants (positions)	Superior implant ending point	Range of motion (°)	Motion increase (°)	% 3 Implant motion
Intact	-	-[1]	1.94	-	-
Inline	3 (S, M, I)	Mid-ala	0.7	Reference configuration	
Inline	2 (S, M, -)	Mid-ala	0.97	0.27	39
Inline	2 (S, -, I)	Mid-ala	0.82	0.12	17
Inline	2 (-, M, I)	-[1]	0.91	0.21	30
Inline	1 (S, -, -)	Mid-ala	1.36	0.66	94
Inline	1 (-, M, -)	-[1]	1.32	0.62	89
Inline	1 (-, -, I)	-[1]	1.25	0.55	79
Inline	3 (S, M, I)	Mid-sacrum	0.63	Reference configuration	
Inline	2 (S, M, -)	Mid-sacrum	0.76	0.13	21
Inline	2 (S, -, I)	Mid-sacrum	0.69	0.06	10
Inline	1 (S, -, -)	Mid-sacrum	1.21	0.58	92
Transarticular	3 (S, M, I)	Mid-ala	0.59	Reference configuration	
Transarticular	2 (S, M, -)	Mid-ala	0.81	0.22	37
Transarticular	2 (S, -, I)	Mid-ala	0.69	0.1	17
Transarticular	2 (-, M, I)	-[1]	0.76	0.17	29
Transarticular	1 (S, -, -)	Mid-ala	1.36	0.77	131
Transarticular	1 (-, M, -)	-[1]	1.11	0.52	88
Transarticular	1 (-, -, I)	-[1]	1.05	0.46	78
Transarticular	3 (S, M, I)	Mid-sacrum	0.52	Reference configuration	
Transarticular	2 (S, M, -)	Mid-sacrum	0.64	0.12	23
Transarticular	2 (S, -, I)	Mid-sacrum	0.58	0.06	12
Transarticular	1 (S, -, -)	Mid-sacrum	1.21	0.69	133
Treatment	**Implants (positions)**	**Superior implant ending point**	**% 3 Implant motion**	**Implants (positions)**	**Median (%) [range]**
Inline	2 (S, -, I)	Mid-ala	17	2 (S, -, I)	14.5% (10-17)
Inline	2 (S, -, I)	Mid-sacrum	10		
Transarticular	2 (S, -, I)	Mid-ala	17		
Transarticular	2 (S, -, I)	Mid-sacrum	12		
Inline	2 (S, M, -)	Mid-ala	39	2 (S, M, -)	30% (21-39)
Inline	2 (S, M, -)	Mid-sacrum	21		
Transarticular	2 (S, M, -)	Mid-ala	37		
Transarticular	2 (S, M, -)	Mid-sacrum	23		
Inline	2 (-, M, I)	-[1]	30	2 (-, M, I)	29.5% (29-30)
Transarticular	2 (-, M, I)	-[1]	29		
Inline	1 (S, -, -)	Mid-ala	94	1 (S, -, -)	112.5% (92-133)
Inline	1 (S, -, -)	Mid-sacrum	92		
Transarticular	1 (S, -, -)	Mid-ala	131		
Transarticular	1 (S, -, -)	Mid-sacrum	133		
Inline	1 (-, M, -)	-[1]	89	1 (-, M, -)	88.5% (88-89)
Transarticular	1 (-, M, -)	-[1]	88		
Inline	1 (-, -, I)	-[1]	79	1 (-, -, I)	78.5% (78-79)
Transarticular	1 (-, -, I)	-[1]	78		

[1]Configuration does not include a superior implant. S: Superior; M: Middle; I: Inferior.

simulate SI joint dysfunction, therefore generalizing the results to the general patient population should be made with care[17]. The current study assumed sacral cancellous bone material properties based on those found in normal cancellous bone (*t*-score > -1). Although the reported bone mineral densities are

Table 5 Change in sacroiliac joint lateral bending range of motion (°) as a result of reducing the number of implants

Treatment	Implants (positions)	Superior implant ending point	Range of motion (°)	Motion increase (°)	% 3 implant motion
Intact	-	-[1]	0.66	-	-
Inline	3 (S, M, I)	Mid-ala	0.45	Reference configuration	
Inline	2 (S, M, -)	Mid-ala	0.5	0.05	11
Inline	2 (S, -, I)	Mid-ala	0.47	0.02	4
Inline	2 (-, M, I)	-[1]	0.53	0.08	18
Inline	1 (S, -, -)	Mid-ala	0.58	0.13	29
Inline	1 (-, M, -)	-[1]	0.65	0.2	44
Inline	1 (-, -, I)	-[1]	0.69	0.24	53
Inline	3 (S, M, I)	Mid-sacrum	0.41	Reference configuration	
Inline	2 (S, M, -)	Mid-sacrum	0.45	0.04	10
Inline	2 (S, -, I)	Mid-sacrum	0.43	0.02	5
Inline	1 (S, -, -)	Mid-sacrum	0.58	0.17	41
Transarticular	3 (S, M, I)	Mid-ala	0.41	Reference configuration	
Transarticular	2 (S, M, -)	Mid-ala	0.45	0.04	10
Transarticular	2 (S, -, I)	Mid-ala	0.42	0.01	2
Transarticular	2 (-, M, I)	-[1]	0.47	0.06	15
Transarticular	1 (S, -, -)	Mid-ala	0.58	0.17	41
Transarticular	1 (-, M, -)	-[1]	0.6	0.19	46
Transarticular	1 (-, -, I)	-[1]	0.62	0.21	51
Transarticular	3 (S, M, I)	Mid-sacrum	0.38	Reference configuration	
Transarticular	2 (S, M, -)	Mid-sacrum	0.41	0.03	8
Transarticular	2 (S, -, I)	Mid-sacrum	0.39	0.01	3
Transarticular	1 (S, -, -)	Mid-sacrum	0.58	0.2	53

Treatment	Implants (positions)	Superior implant ending point	% 3 Implant motion	Implants (positions)	Median (%) [range]
Inline	2 (S, -, I)	Mid-ala	4	2 (S, -, I)	3.5% (2-5)
Inline	2 (S, -, I)	Mid-sacrum	5		
Transarticular	2 (S, -, I)	Mid-ala	2		
Transarticular	2 (S, -, I)	Mid-sacrum	3		
Inline	2 (S, M, -)	Mid-ala	11	2 (S, M, -)	10% (8-11)
Inline	2 (S, M, -)	Mid-sacrum	10		
Transarticular	2 (S, M, -)	Mid-ala	10		
Transarticular	2 (S, M, -)	Mid-sacrum	8		
Inline	2 (-, M, I)	-[1]	18	2 (-, M, I)	16.5% (15-18)
Transarticular	2 (-, M, I)	-[1]	15		
Inline	1 (S, -, -)	Mid-ala	29	1 (S, -, -)	41% (29-53)
Inline	1 (S, -, -)	Mid-sacrum	41		
Transarticular	1 (S, -, -)	Mid-ala	41		
Transarticular	1 (S, -, -)	Mid-sacrum	53		
Inline	1 (-, M, -)	-[1]	44	1 (-, M, -)	45% (44-46)
Transarticular	1 (-, M, -)	-[1]	46		
Inline	1 (-, -, I)	-[1]	53	1 (-, -, I)	52% (51-53)
Transarticular	1 (-, -, I)	-[1]	51		

[1]Configuration does not include a superior implant. S: Superior; M: Middle; I: Inferior.

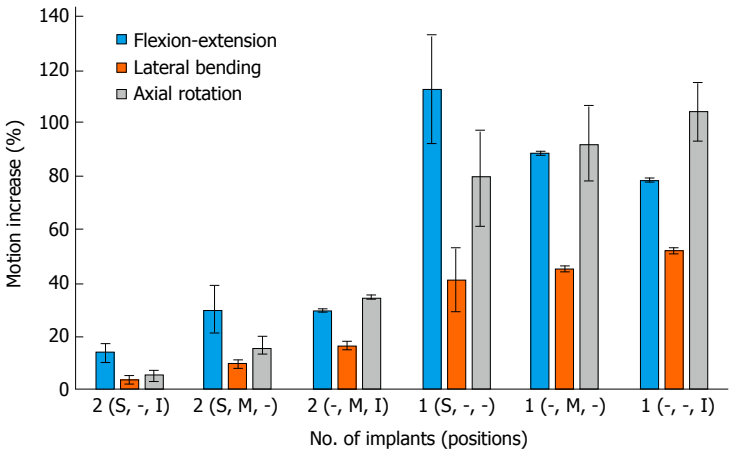

Figure 2 Motion increase (%) for configurations with a reduced number of implants. The increase for each condition was normalized by the corresponding model that contained 3 implants. Note that a smaller increase in motion represents more reduction in range of motion. S: Superior; M: Middle; I: Inferior. Data is shown as median ± range.

Table 6 Change in sacroiliac joint axial rotation range of motion (°) as a result of reducing the number of implants

Treatment	Implants (positions)	Superior implant ending point	Range of motion	Motion increase (°)	% 3 implant motion
Intact	-	[1]	1.11	-	-
Inline	3 (S, M, I)	Mid-ala	0.41	Reference configuration	
Inline	2 (S, M, -)	Mid-ala	0.49	0.08	20
Inline	2 (S, -, I)	Mid-ala	0.44	0.03	7
Inline	2 (-, M, I)	[1]	0.55	0.14	34
Inline	1 (S, -, -)	Mid-ala	0.67	0.26	63
Inline	1 (-, M, -)	[1]	0.73	0.32	78
Inline	1 (-, -, I)	[1]	0.79	0.38	93
Inline	3 (S, M, I)	Mid-sacrum	0.38	Reference configuration	
Inline	2 (S, M, -)	Mid-sacrum	0.43	0.05	13
Inline	2 (S, -, I)	Mid-sacrum	0.4	0.02	5
Inline	1 (S, -, -)	Mid-sacrum	0.61	0.23	61
Transarticular	3 (S, M, I)	Mid-ala	0.34	Reference configuration	
Transarticular	2 (S, M, -)	Mid-ala	0.4	0.06	18
Transarticular	2 (S, -, I)	Mid-ala	0.36	0.02	6
Transarticular	2 (-, M, I)	[1]	0.46	0.12	35
Transarticular	1 (S, -, -)	Mid-ala	0.67	0.33	97
Transarticular	1 (-, M, -)	[1]	0.7	0.36	106
Transarticular	1 (-, -, I)	[1]	0.73	0.39	115
Transarticular	3 (S, M, I)	Mid-sacrum	0.31	Reference configuration	
Transarticular	2 (S, M, -)	Mid-sacrum	0.35	0.04	13
Transarticular	2 (S, -, I)	Mid-sacrum	0.32	0.01	3
Transarticular	1 (S, -, -)	Mid-sacrum	0.61	0.3	97
Treatment	**Implants (positions)**	**Superior implant ending point**	**% 3 Implant motion**	**Implants (positions)**	**Median (%) [range]**
Inline	2 (S, -, I)	Mid-ala	7	2 (S, -, I)	5.5% (3-7)
Inline	2 (S, -, I)	Mid-sacrum	5		
Transarticular	2 (S, -, I)	Mid-ala	6		
Transarticular	2 (S, -, I)	Mid-sacrum	3		
Inline	2 (S, M, -)	Mid-ala	20	2 (S, M, -)	15.5% (13-20)
Inline	2 (S, M, -)	Mid-sacrum	13		
Transarticular	2 (S, M, -)	Mid-ala	18		
Transarticular	2 (S, M, -)	Mid-sacrum	13		
Inline	2 (-, M, I)	[1]	34	2 (-, M, I)	34.5% (34-35)
Transarticular	2 (-, M, I)	[1]	35		
Inline	1 (S, -, -)	Mid-ala	63	1 (S, -, -)	80% (61-97)
Inline	1 (S, -, -)	Mid-sacrum	61		
Transarticular	1 (S, -, -)	Mid-ala	97		
Transarticular	1 (S, -, -)	Mid-sacrum	97		
Inline	1 (-, M, -)	[1]	78	1 (-, M, -)	92% (78-106)
Transarticular	1 (-, M, -)	[1]	106		
Inline	1 (-, -, I)	[1]	93	1 (-, -, I)	104% (93-115)
Transarticular	1 (-, -, I)	[1]	115		

[1]Configuration does not include a superior implant. S: Superior; M: Middle; I: Inferior.

different in the normal, osteopenic, and osteoporotic sacra, the distribution of low and high density locations are consistent in all three cases[19,24]; as such, we expect that the findings in the different bone quality groups will be consistent. The current model and previous experimental study had consistent intact ROM and motion reductions after treatment, but there are some differences for the loading conditions simulated in this study (double-leg stance, follower load, and larger applied moment). Although the loading conditions were different, the consistency in intact ROM suggested that these disparities were counteracting each (*e.g.,* follower load and double-leg stance increase stability; higher applied moment increase ROM)[17], and demonstrated that the SI joint and treatment were being effectively modeled. Lastly, the theoretical model used in this study did not model all *in vivo* characteristics (*e.g.,* biological healing response after surgery); as such, additional clinical studies may be required to confirm these results.

While the minimum biomechanical requirements for clinically successful fixation of the SI joint are currently unknown, the current study investigated 3 clinical implant placement parameters and compared the resulting SI joint reduction in range of motion with a baseline model. The baseline model investigated here (inline orientation, mid-ala superior implant length, 3 implants) is a common technique that has positive clinical outcomes[23]. The range of motion of the SI joint in the current study was assessed in 3 anatomical loading directions, of which flexion-extension demonstrated both the largest intact range of motion (1.94°) and, after treatment, overall reductions in motion (0.58°-1.42°). Lateral bending and axial rotation resulted in small median reductions in motion (< 0.1°) when the variables were investigated, which may not be clinically significant by themselves. In contrast, flexion-

extension was more sensitive to altering the variables with median reductions in motion > 0.1°. Although the 3 motions investigated had varying sensitivity, they consistently (*i.e.,* positively/negatively) altered the reductions in motion. These results demonstrate that in flexion-extension, when compared with the baseline model, placement of the implants in areas of thicker cortical bone (transarticular orientation) and higher bone density (longer superior implant) leads to similar median increased reductions in motion of 16% and 14%, respectively. This study suggests that a surgeon can optimize implant placement in 3 ways: (1) Longer superior implants; (2) transarticular placement; and (3) using 3 implants (and/or increasing implant separation). Although the long-term clinical outcomes from these placement variations is unknown, the current study provides clinicians with insight and rationale into determining optimal implant placement.

ARTICLE HIGHLIGHTS

Research background

Minimally invasive fusion of the sacroiliac (SI) joint is a potential treatment for patients suffering with symptoms related to the SI joint. The use of a lateral procedure for SI joint fusion has been shown to be an effective method for reducing SI joint pain. Previous anatomical studies have demonstrated significant variability in sacral anatomy and the resultant location and size of safe zones for implant placement.

Research motivation

A surgeon has options regarding the number of implants, length of implants, and their orientation; the optimal placement parameters for SI joint fixation are currently unknown. Quantification of the changes in SI joint motion as a result of varying the potential implant placement variables will provide a surgeon input when performing an SI joint fusion procedure.

Research objectives

The objective of this study was to investigate and quantify the effect of implant orientation, superior implant length, and implant number on SI joint range of motion.

Research methods

This study used a previously validated finite element analysis to investigate how implant orientation, superior implant length, and implant number affect SI joint range of motion. Implant orientation was simulated using either an inline or a transarticular placement. The length of the superior implant was varied to end either in the middle of the ala or at the sacral midline. The number of implants was 1, 2, or 3 implants. The SI joint range of motion was calculated using a constant moment of 10 N-m with a follower load of 400 N in flexion-extension, lateral bending, and axial rotation. A total of 23 model configurations were tested and the difference in SI joint range of motion compared.

Research results

The use of a transarticular placement with a mid-sacrum length superior implant resulted in the greatest reduction in SI joint ROM. The use of transarticular placement resulted in median reductions in motion of 16%, 9%, and 18%, in flexion-extension, lateral bending, and axial rotation, respectively. Extending the superior implant to the sacral midline resulted in median reductions in motion of 14%, 8%, and 9%, in flexion-extension, lateral bending, and axial rotation, respectively. Reducing the number of implants (*i.e.*, 1 or 2 implants) resulted in increased motions in all directions. Implant configurations with 2 implants placed farthest apart had the smallest increases.

Research conclusions

This study demonstrates that the treated SI joint range of motion is affected by implant orientation, superior implant length, and implant number. These results show that the optimal placement investigated was 3 implants placed using a transarticular placement with a superior implant that reaches the sacral midline. This study suggests that a surgeon can optimize implant placement in 3 ways: (1) Longer superior implants; (2) transarticular placement; and (3) using 3 implants (and/or increasing implant separation).

Research perspectives

The use of a finite element model to simulate the SI joint and treatment effects allows for investigation of many variables and provides valuable insight regarding how each variable effects SI joint stability. These results allow for more detailed investigation using either *in vitro* or *in vivo* studies.

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ORIGINAL ARTICLE

Retrospective Study

Complex knee injuries treated in acute phase: Long-term results using Ligament Augmentation and Reconstruction System artificial ligament

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Author contributions: Gliatis J has designed the research; Anagnostou K conducted the data collection, analysis and wrote the manuscript; Gliatis J and Plessas S were the senior surgeons; Billis E and Papandreou M were the senior physiotherapists of the team.

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Abstract

AIM

To present the long-term results of complex knee injuries, treated early using the Ligament Augmentation and Reconstruction System (LARS) artificial ligament to reconstruct posterior cruciate ligament (PCL).

METHODS

From September 1997 to June 2010, thirty-eight complex knee injuries were treated, where early arthroscopic PCL reconstructions were undergone, using the LARS (Surgical Implants and Devices, Arc-sur-Tille, France) artificial ligament. Exclusion criteria were: Late (> 4 wk) reconstruction, open technique, isolated PCL reconstruction, knee degenerative disease, combined

fracture or vascular injury and use of allograft or autograft for PCL reconstruction. Clinical and functional outcomes were assessed with IKDC Subjective Knee Form, KOS-ADLS questionnaire, Lysholm scale and SF-12 Health Survey. Posterior displacement (PD) was measured with the Telos Stress Device.

RESULTS

Seven patients were excluded; two because of co-existing knee osteoarthritis and the remaining five because of failure to attend the final follow-up. The sample consisted of 31 patients with mean age at the time of reconstruction 33.2 ± 12.5 years (range 17-61). The postoperative follow-up was on average 9.27 ± 4.27 years (range 5-18). The mean average IKDC and KOS scores were 79.32 ± 17.1 and 88.1 ± 12.47% respectively. Average PD was 3.61 ± 2.15 mm compared to 0.91 ± 1.17 mm in the uninjured knees (one with grade 1 + and two with grade 2 +). Dial test was found positive in one patient, whereas the quadriceps active drawer test was positive in three patients. None was tested positive on the reverse-pivot shift test. The range of motion (ROM) was normal in thirty knees, in comparison with the contralateral one. There was no extension deficit. Osteoarthritic changes were found in three knees (9.6%).

CONCLUSION

Early treatment of complex knee injuries, using LARS artificial ligament for PCL reconstruction sufficiently reduces posterior tibia displacement and provides satisfactory long-term functional outcomes.

Key words: Complex knee injuries; Posterior cruciate ligament; Acute reconstruction; Ligament Augmentation and Reconstruction System

Core tip: Complex knee injuries pose a difficult problem while the treatment remains controversial. There are only few studies with long-term follow-up and with homogenous sample, regarding the timing of operation, the type of the graft and the type of reconstruction. In our study with a long-term follow-up, we have operated all the patients in the acute phase, using a standardized protocol regarding the technique, the type of the graft and the postoperative rehabilitation. Furthermore we have excluded the knee dislocations with vascular injuries, since these injuries have a different prognosis and they consist a separate category.

Gliatis J, Anagnostou K, Tsoumpos P, Billis E, Papandreou M, Plessas S. Complex knee injuries treated in acute phase: Long-term results using Ligament Augmentation and Reconstruction System artificial ligament. *World J Orthop* 2018; 9(3): 24-34 Available from: URL: http://www.wjgnet.com/2218-5836/full/v9/i3/24.htm DOI: http://dx.doi.org/10.5312/wjo.v9.i3.24

INTRODUCTION

Although most complex knee injuries are thought to occur due to a knee dislocation, in real practice a complete knee dislocation is very rare. Almost all complex knee injuries involve either the anterior cruciate ligament (ACL) and/or posterior cruciate ligament (PCL). This may be combined with injury to the medial knee structures and/or posterolateral corner structures of the knee. "Benign knee dislocation", described by Wascher *et al*[1] features isolated knee injury with mild or no neurovascular compromise and intact bony structure. Controversies also exist regarding various parameters, including early *vs* delayed surgery, type of reconstruction technique being chosen and postoperative rehabilitation program[2,3]. Very few studies exist with long term follow-up, whilst most of them include cases with complex injuries and true dislocations being classified within the same category.

Amongst the controversies regarding reconstruction of the multiple-injured knee is the choice of PCL graft tissue and the timing of the operation[4]. Posterior cruciate ligament is considered the primary restraint to posterior translation of the knee and the central stabilizer of the knee[5-8]. The incidence of PCL injuries is lower than that of ACL, occurring in approximately 3.4% to 20% of all knee ligament injuries[9]. PCL injuries are presented either as isolated tears or combined with other knee ligament injuries. Multiple knee ligament injuries usually need surgical treatment[10,11]. Despite the variety of operative techniques, PCL reconstruction still remains a challenge[10,12,13]. Autografts like Patella tendon (Bone-Tendon-Bone), Hamstrings and Quadriceps tendon or allografts like Achilles tendon, Anterior and Posterior Tibialis tendon are the most commonly used grafts[4]. Artificial grafts are rarely indicated because of their previous failure in ACL reconstruction[14-16]. The new generation artificial ligaments offer the advantages of less surgical time, absence of donor site morbidity, avoidance of possible spread of diseases (like Hepatitis C, HIV or knee infection), and faster postoperative rehabilitation[4,17-21].

As far as the timing of the operation is concerned, previous studies have stress out the risk of arthofibrosis after early treatment[22,23]. However in other reports, there is evidence that early reconstruction, in the first 4-6 wk usually provides better results compared to delayed reconstruction[2,24], which could be explained by the good healing capacity of the early ruptured PCL[25-29]. The limit of early treatment though arbitrary is considered 3 wk. Recently Fanelli *et al*[3] set the limit of early reconstruction in six weeks long.

In our retrospective study we have included patients with complex knee injuries being treated acutely and followed-up long-term, utilizing a standardized treatment protocol. Early (during 4 wk post injury) PCL reconstruction using an artificial ligament as a temporary restraint to posterior translation of tibia,

Table 1 Patients data

Patient	Gender	Age	Cause and time of Injury	Injury	Operation time after injury (wk)	Follow-up (yr)
1	Male	35	MVA (2007)	(R) PCL/MCL/MM	2	8
2	Male	46	MVA (2007)	(R)PCL/ACL/MCL part	4	8
3	Male	52	MVA (2003)	(L) PCL/ACL/LM	1	12
4	Male	19	MVA (2004)	(R) PCL/PLC/LM	4	11
5	Male	41	MVA (1997)	(L) PCL/ACL/LM	2	18
6	Male	36	MVA (2003)	(L) PCL/ACL	1	12
7	Male	25	MVA (2007)	(R) PCL/ACL/PLC	4	8
8	Male	20	MVA (2001)	(L) PCL/MCL/MM	4	14
9	Male	61	FALL (2006)	(R) PCL/ACL/MCL	1	9
10	Male	60	FALL (2007)	(R) PCL/ACL/PLC	3	8
11	Fem.	54	FALL (2000)	(R) PCL/ACL/	3	15
12	Male	37	MVA (2002)	(R) PCL/ACL	3	13
13	Male	25	MVA (2004)	(R)PCL/PLC/ACL/LM	1	11
14	Male	51	MVA (2007)	(L) PCL/MCL	4	8
15	Female	17	FALL (1999)	(L)PCL/ACL/LM	1	16
16	Female	28	FALL (2005)	(R)PCL/ACL/MCL part	1	10
17	Male	20	MVA (2000)	(L) PCL/MCL	4	15
18	Male	23	MVA (2003)	(R) PCL/PLC/LM	2	12
19	Male	38	MVA (2004)	(L) PCL/MCL	3	11
20	Male	37	MVA (2007)	(R) PCL/PLC	2	8
21	Male	27	FALL (2009)	(L) PCL/ACL	4	6
22	Female	36	MVA (2009)	(R) PCL/ACL/PLC	4	6
23	Male	33	MVA (2009)	(R) PCL/ACL/MCL/MM	4	6
24	Male	30	MVA (2010)	(L) PCL/ACL	1	5
25	Male	27	MVA (2010)	(L) PCL/ACL/PLC	3	5
26	Male	21	MVA (2010)	(R) PCL/ACL/MCL	2	5
27	Male	22	MVA (2011)	(R) PCL/ACL	1	6
28	Male	35	FALL (2010)	(R) PCL/ACL	4	5
29	Male	26	MVA (2010)	(R) PCL/ACL/MCL	2	5
30	Male	26	MVA (2010)	(R) PCL/ACL/MCL	4	5
31	Male	21	MVA (2011)	(R) PCL/ACL	4	7
Average ± SD		33.2 ± 12.5			2.67 ± 1.24	9.2 ± 4.27

allows the PCL remnants to heal[26,30-35] and can give satisfactory early and long-term results concerning posterior stability. In addition the augmentation of the posterolateral corner reconstruction allows the repaired soft tissues to heal in the correct position. We thus, retrospectively present the results of complex knee injuries treated in the early post-injury period using the artificial ligament LARS (Ligament Augmentation Reconstruction System)[36-38] to reconstruct PCL. The purpose of this study was to post-operatively assess the stability and clinical outcomes of the knee in mid-term to long-term follow-up, and to identify the progress of any degenerative changes in acutely operated knees.

MATERIALS AND METHODS

Sample

Multiple ligament knee injuries where PCL was reconstructed with LARS artificial ligament were retrospectively studied. The study period was from 1997 to 2010. Thirty-eight operations were undergone in this period. Inclusion criteria were the early arthroscopically-assisted, multiple ligament reconstruction, always including single bundle PCL reconstruction with LARS artificial ligament. Exclusion criteria were the open technique, the use of allografts or autografts such Hamstrings or Patella tendon for PCL reconstruction, the isolated PCL reconstruction, the presence of degenerative knee disease and the concomitant fracture or vascular injury that could influence the postoperative rehabilitation program. All patients were operated in the first four weeks after injury, which is the elapsed time to consider an injury as an acute one (Table 1).

Graft selection

The graft used for PCL reconstruction was the LARS (Ligament Augmentation and Reconstruction System, Surgical Implants and Devices, Arc-sur-Tille, France) artificial ligament, made of polyethylene terephthalate. LARS is a system of artificial ligament devices used for ACL, PCL, PLC (posterolateral corner) reconstructions and also Achilles tendon ruptures and acromioclavicular joint injuries[18,19,36,37,39]. We have used PC 80 in our cases.

Operative technique

All the operations were performed by the two senior authors, which were experienced in multiple ligament reconstructions. Under general anesthesia in supine position, a tourniquet was applied to the affected limb without being inflated. The foot of the operated leg was seated on a post over the operative table with a lateral support to maintain the knee in 90° of flexion. Leg position adjustments were possible. We used fluids with

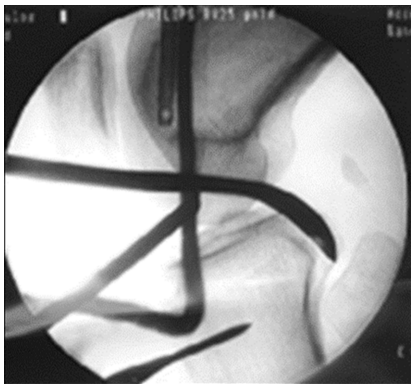

Figure 1 Tibial tunnel opening under image intensifier.

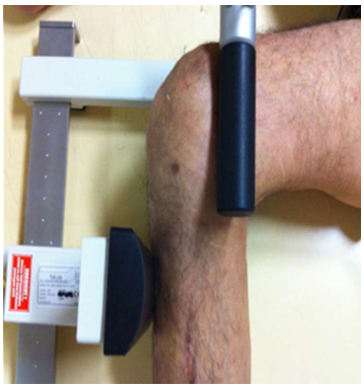

Figure 2 Proper position of tibia and femur for Telos Stress Device.

gravity flow and not a pump. An image intensifier was necessary in the theatre. In all cases, we performed a routine arthroscopic examination of the knee joint through the standard anterolateral and anteromedial portals. These portals were made immediately adjacent to the lateral and medial borders of the patellar tendon and 1 cm above the joint line to allow an easy passage of an arthroscope through the intercondylar notch to provide access to PCL tibial attachment. In PCL injuries, it is easier for the arthroscope to pass from the anterolateral portal to the posteromedial compartment through the intercondylar notch. In cases of meniscal or cartilage injury, if debridement was needed, the medial portal was used as well. Posteromedial portal was not used. Initial intra-articular bleeding was controlled with the aid of intermittent tourniquet inflation. A thorough evaluation of the intra-articular injuries was performed. The meniscal and cartilage injuries were treated first, either with fragments removal or meniscal repair. In all cases PCL was reconstructed, first of all injured ligaments, with LARS artificial ligament. The PCL remnants were always left intact and the tibial tunnel was created first, under image intensifier control (Figure 1). With the LARS instrument there was no need to debride the tibial PCL attachment. Then the femoral tunnel was created aiming just inferior to the native anterolateral bundle attachment of the PCL. The graft was passed afterwards through the tunnels with the aid of flexible wires, leaving the functional part of the graft inside the knee joint. The femoral side was fixed first and the normal step off was restored under image intensifier before the fixation of the tibial side with one screw and one staple. In cases of coexisting ACL rupture, we reconstructed the ligament in the early cases with LARS artificial ligament in the first 12 cases, while in the other 13 cases we used Hamstrings tendons. Posterolateral instability (PLI) was detected clinically with increased external rotation (Dial test) and arthroscopically with the "drive through sign" in 9 cases. We reconstructed posterolateral corner (PLC) addressing the popliteal and popliteo-fibular ligament (Warren procedure)[35,40]. In all cases we used Hamstrings tendons from the contralateral knee to augment the repaired PLC structures. In none of the cases MCL reconstruction was necessary[41]. Postoperatively we used continuous passive motion (CPM) from day one. The patients were allowed to partial weight-bear for 6 wk and gradually to full weight-bear up to two months. Postoperatively conventional functional braces were utilized[20,21].

Evaluation

All patients were assessed clinically and functionally in an outpatient office by an independent observer who was an appropriately trained senior resident. Clinical evaluation included Lachman and reverse-Lachman test, Anterior and Posterior Drawer tests (grading: 1 +: 0-5 mm, 2 +: 5-10 mm, 3 +: > 10 mm anterior or posterior translation respectively), Quadriceps Active Drawer test, Dial test for PLI and Varus-Valgus stress tests (grading Ⅰ: 0-5 mm, Ⅱ: 5-10 mm, Ⅲ: > 10 mm opening) for collateral ligaments' assessment[42]. The functional outcome was assessed with ROM evaluation, KOS-ADLS score and IKDC Subjective Knee Form, while Lysholm knee scoring, and SF-12 Health Survey completed the clinical outcomes[43-47]. The examiner used the Telos Stress Device to evaluate the posterior displacement of the injured knee in comparison to the contralateral healthy one[48,49]. A lateral x-ray imaging was performed in 90° of knee flexion under a standard anteroposterior force of 150N from Telos Stress Device (Figure 2). The standard force is widely accepted since 80N are adequate to induce posterior displacement of the tibia, while a greater than 180N force will cause pain and muscle contraction, influencing the reliability of measurements[50]. The total posterior tibial translation was measured and the side to side difference between normal and affected knee was compared during the force applied and not[50-53] (Figure 3). Arthritis was assessed by AP radiographs. Arthritis was rated as either present or absent based on joint space narrowing and/or the presence of osteophytes. This methodology is similar to that used in the Kellgren and Lawrence (KL) grading system[54]. Patients without evidence of osteoarthritis would be considered (KL) Grade 0 to 1, whereas patients with radiographic evidence of

Table 2 Functional scores

Patient code	KOS-ADSL/70 × 100%	IKDC/87 × 100	Lysholm/100	SF-12	
				Physical subscale (%)	Mental subscale (%)
1	94.2%	88.5	91	51.1	62.4
2	98.5%	79.3	100	54.8	59.8
3	88.5%	83.9	85	49.3	61.4
4	95.7%	98.8	91	56.6	60.8
5	92.8%	77.0	88	56.6	60.8
6	74.2%	65.5	83	48.7	61.5
7	98.5%	98.8	100	56.6	60.8
8	100%	94.2	100	57.2	33.8
9	88,5%	62.0	94	48.0	62.5
10	100%	98.5	100	56.6	60.8
11	77.1%	72.0	88	56.6	60.8
12	78.5%	80.4	90	53.1	59.9
13	88.5%	83.9	69	53.0	57.0
14	41.4%	24.1	48	30.8	40.5
15	90.0%	93.1	85	56.6	60.8
16	100%	95.4	100	56.6	60.8
17	80.0%	52.8	90	38.8	61.5
18	75.7%	60.9	58	47.6	48.6
19	85.7%	81.6	95	54.1	53.8
20	97.1%	95.4	99	56.6	60.8
21	90.0%	81.6	99	55.3	60.7
22	97.1%	95.4	99	55.3	60.7
23	58.5%	49.4	67	42.8	57.0
24	92.8%	81.6	94	55.3	60.7
25	98.5%	100	100	56.6	60.8
26	92.8%	86.2	85	53.2	49.8
27	95.7%	90.8	94	56.6	60.8
28	77.1%	55.1	81	36.0	60.4
29	98.5%	89.6	94	56.6	60.8
30	92.8%	85.0	94	56.6	60.8
31	92.8%	81.6	86	55.3	60.7
Average ± SD	88.1 ± 12.47	79.32 ± 17.1	88 ± 12.4		

osteoarthritis would be considered (KL) Grade 2 to 4.

RESULTS

Thirty-eight patients in total over the 17 years' period sustained a complex knee injury including PCL rupture and underwent a reconstruction of PCL with LARS artificial ligament. From these, two patients were excluded because of co-existing knee osteoarthritis, while five more did not manage to attend the final follow-up. So, the final sample consisted of 31 patients. From the 31 patients, 27 were males and 4 females. From the reconstructed knees 20 were right side and 11 left. The mean age at the time of reconstruction was 34.5 (± 12.5) years (range 17-61). The average time from injury to surgery was 2.67 (± 1.24) wk (range 1-4) and the mean time of postoperative follow-up was 9.2 (± 4.27) years (range 5-18), (Table 1). From the 31 cases, 24 were motor vehicle accidents (MVA) and 7 were sport injuries and falls (Table 1). All patients were examined clinically (clinical examination) functionally (with functional outcome questionnaires) (Table 2), and radiologically with the Telos stress device (Table 3).

Time interval between injury and operation

Three patients (8.8%) were operated during the first week (< 1/52); specifically two patients were operated three days post-injury and one patient on the accident day. Also five patients (17.6%) were operated 1 wk (1/52) after the trauma and six patients (17.6%) 2 wk (2/52) after their accident, respectively. Five patients (17.6%) underwent operation three weeks (3/52) post injury, while twelve patients (38.2%) were treated four weeks (4/52) after injury.

Functional scores and clinical findings

The mean KOS-ADLS score (Knee Outcome Survey - Activities of Daily Living Score) was 88.1% (± 12.47). Twenty-two patients (70.9%) had score greater than 60/70 and two of them (6.4%) reached the absolute 70/70, indicating excellent functionality. Only one patient (3.2%) had score of less than 35/70. The mean IKDC (International Knee Documentation Committee) Subjective Knee Form was 79.32 (± 17.1). Twenty patients (64.5%) reached 70/87 score and above but four patients (12.9%) pointed a score lower than 50/87.

The evaluation according to the Lysholm knee scoring revealed excellent (95-100) results for ten (32.2%) patients, good (84-94) for sixteen (51.6%), fair (65-83) for three (9.6%) and poor (< 64) for only two (6.4%) patients (Table 2). Regarding the SF-12 Health Survey, all patients except three declared very satisfied from

Table 3 Radiological results with Telos device

Patient code	Telos posterior displacement (mm) X-ray measured	
	Operated knee	Healthy knee (contralateral)
1	8	0
2	6	3
3	5	2
4	1	0
5	4	0
6	2	5
7	0	0
8	0	2
9	6	0
10	3	1
11	2	1
12	4	0
13	6	1
14	7	2
15	5	0
16	3	3
17	3	0
18	3	0
19	4	1
20	3	1
21	4	0
22	2	1
23	8	0
24	4	1
25	0	2
26	5	0
27	1	1
28	3	0
29	0	0
30	3	0
31	4	0
Average (SD)	3.61 (± 2.15)	0.91 (± 1.17)

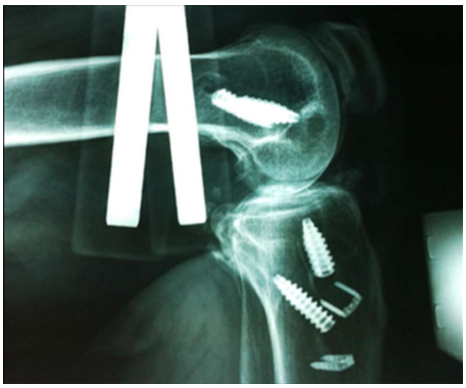

Figure 3 Anteroposterior force on tibia through Telos Device leading to posterior translation.

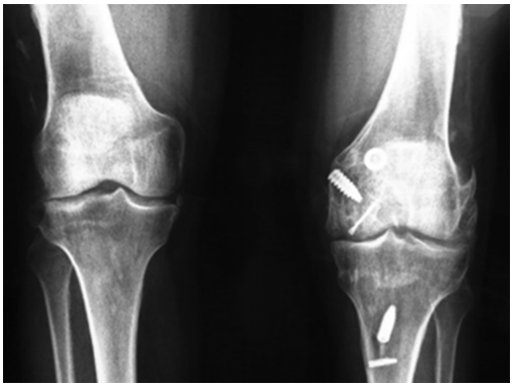

Figure 4 Anteroposterior knee x-rays for evaluation of arthritis progression (Kellgren and Lawrence grade 3).

the postoperative outcome in both physical and mental health fields (ranging from 30.8-56.6 and 33.8-62.5 respectively), and further indicated that if again needed, they would undergo the same procedure under the same circumstances (Table 3).

The posterior drawer test was positive (grade 2 +) in six (n = 6) patients, the anterior drawer test was positive in three (n = 3) (one with grade 1 + and two with grade 2 +), the varus stress test in five (n = 5) (three with grade Ⅰ and two with grade Ⅱ) and the valgus stress test in three (n = 3) patients (all with grade Ⅱ). The dial test was found positive (> 15° side to side difference) in one (n = 1) patient, whereas the quadriceps active drawer test was positive in three (n = 3) patients. None was tested positive on the reverse-pivot shift test. The range of motion (ROM) was normal in thirty knees, in comparison with the contralateral one, with a 0°-121.2° (± 10.14) average flexion arc and had no extension deficit. Only in one knee there was a limitation of ROM: 0°-90°.

Radiographic evaluation

The evaluation of knee X-rays (AP weight-bearing-standing) revealed a medial joint space narrowing (> 2 mm in comparison with lateral joint space) in three (n = 3) patients; in a 66 year old woman at the last follow-up, 15 years postoperatively with (KL) grade 3 (Figure 4), and in two men 64 and 54 years old, 8 and 15 years after operation, respectively both with (KL) grade 2. The remaining twenty-eight (n = 31) patients had no radiographic findings of joint space narrowing (KL grade 0 or 1). The mean tibial posterior displacement of the operated knees as measured with the Telos Stress Device was 3.61 (± 2.15) mm. The value for the normal contralateral knees was 0.91 (± 1.17) mm respectively. Twenty-five patients (80.6%) were found with posterior translation of less than 5 mm (Grade Ⅰ) and six patients (19.3%) with posterior displacement in the range 6-10 mm (Grade Ⅱ). No one patient was classified in the group of 11-15 mm or greater than 15 mm (Grades Ⅲ and Ⅳ, respectively) (Table 3).

DISCUSSION

In our study we treated complex knee injuries in the acute phase, at four weeks' time, reconstructing PCL with LARS artificial ligament in all our cases. The clinical outcome was satisfactory in most of the cases long-term. The rate of posttraumatic arthritis was very low, too. Most of our patients in this study maintained a good clinical outcome in the long-term follow-up. We assessed the stability with the Telos Stress Device

postoperatively[48-53]. The posterior translation was more than 5 mm in only six patients, but none of them had an over 10 mm posterior displacement. The mean side-to-side difference was 2.7 mm, which is comparable with other series with long-term follow-ups. Hermans *et al*[55] found a 4.7 mm mean difference in their patients. Similar results have been reported in other studies using autografts or allografts[56]. The functional and clinical outcome was assessed through three knee-specific questionnaires: The IKDC Subjective Knee Form, the KOS-ADLS, the Lysholm scale, as well as a general health questionnaire, the SF-12 Health Survey[43-45]. More than 70% of our patients scored good to excellent results in all measures used. Only one patient yielded disappointing results even though the objective assessment was normal. In our study the rate of post-traumatic arthritis was low (three out of 34 patients) compared to other studies with similar follow-up time[3,57,58].

Very few studies underwent long-term follow-up[2,3,57-61] and only two studies exceeded the ten-year follow-up limit[3,59]. However most of these previous studies included both true dislocations and complex knee injuries together. Thus, making the sample heterogeneous, because the soft tissue injury is usually worse after a complete dislocation. In one of those, Engebretsen *et al*[58] also included patients with different type of injuries, where they concluded that high-energy injuries had significantly lower functional scores. Furthermore in some of these studies with long term follow-up the type of treatment was not consistent, either treating the patients in two stages[57] or conservatively[61]. Another issue, which was not consistent in these studies, was the timing of operative treatment. In some of those the operation was performed in a later stage[57], in others in an early stage[58,59] and some of these studies included patients, who had treatment both in early and late stage[58]. Recently, a study[2] presented good results after long-term follow-up in patients with traumatic knee dislocations. However they included patients with vascular injury requiring repair, as well as some patients with high-energy injuries. In these cases, soft tissues very rarely heal in the first three weeks after the injury making impossible reconstruction in early stage, thus influencing negatively the final outcome. Treatment regime was not the same for all the patients since they used various grafts for ligament reconstruction, especially for the PCL. The incidence of posttraumatic arthritis also, was not reported. Fanelli *et al*[3], presented the study with the longest follow-up (over 10 years) and the patients had a standardized treatment protocol, utilizing allografts in a delayed fashion in the majority of the cases. They reported that the knee stability was restored but one fourth of the patients had developed post-traumatic arthritis. Interestingly, the same authors in a previously reported study[62] with 10 years follow-up did not provide any information about post-traumatic arthritis. Engebretsen *et al*[58] on the other hand reported high incidence of arthritis in his patients but they included all high-energy traumatic complete knee dislocations.

Our treatment regime included several standardized procedures. Firstly, the requirement for operating was to have a "quiet" knee with no blisters or edema, and with smooth range of knee motion. In all of our cases we achieved this goal using early CPM and active quadriceps exercises, at the limits of the pain. Therefore, we excluded the cases of knee dislocations requiring revascularization, as in these cases the repair had to be protected with knee immobilization, using an external fixator. This is the reason we used the term "complex" knee injuries and not knee dislocations. In our experience, the latter is a different entity because of the severity of the soft tissue injury and the possible fasciotomies, associated with vascular reconstruction, which usually preclude early treatment of the knee ligaments. Secondly, our aim was to operate in an early stage, trying to preserve the remnants of both, the ruptured PCL and the ruptured collateral ligaments. There is debate in the literature regarding the timing for treating complex knee injuries. Two systematic reviews, published both in 2009[63,64] reported different conclusions regarding the timing of the operation. Levy *et al*[63] suggested that early operative treatment of the multi-ligament injured knee yields improved functional and clinical outcomes compared to non-operative management or delayed surgery. On the other hand, Mook *et al*[24] reported that delayed reconstructions of severe multiple-ligament knee injuries could potentially yield equivalent outcomes in terms of stability when compared with acute surgery. This is justified by the fact that acute surgery is highly associated with range-of-motion deficits. Hirschmann *et al*[59] reported in 12 years follow-up (average) study with early reconstruction very good results regarding knee stability, but one fifth of the patients had extension deficits and one third of the patients had not satisfactory clinical outcome. The authors did not include patients with vascular repair but the ligament reconstruction was performed with open surgery. Recently Khakha *et al*[2] reported a high level of overall knee function following acute surgical reconstruction with a 10-year average follow-up. However, the treatment protocol was not consistent, since they used different grafts for PCL and PLRI reconstruction. They also included patients requiring vascular repair, who needed postoperative immobilization; they however, have reported immediate knee motion postoperatively.

We have used also the artificial LARS ligament to reconstruct PCL. The artificial graft acts as a scaffold for the PCL remnants. The stable joint environment and the scaffold function of the LARS ligament promotes the healing procedure[25,27,29,31,32,39,51]. Its use in ACL reconstruction as an isolated graft is contraindicated because it has failed in the majority of the cases

even though it seemed successful in the short-term[14-17,26,37,41,64]. The difference in PCL reconstruction is that the function of the graft in the acute phase is to acts as the central support system, allowing the PCL remnants to heal in the correct position with minimal posterior laxity in the knee[30,31,34,65]. Another advantage of the artificial graft is that there is no need for intensive postoperative rehabilitation using sophisticated devices. In all the cases we did not restrict the range of motion postoperatively. The surgical technique also is simpler than the conventional PCL reconstruction techniques, because the posterior portals are not needed, since the posterior exit of the tibial tunnel is assessed fluoroscopically, using the special guide of the LARS system. The risk of synovitis was reduced as we did not notice any case of synovitis in our sample and we are aware of only one case in the literature[14,15]. Another benefit of this reconstructive procedure is that it permits fast return to daily activities and sooner to sports. In contrast to this fast return, hamstrings or other autografts require a period of graft revascularization, where activities are limited and rehabilitation program is extended. In addition, allografts always pose the risk of disease transmission[18,20,21]. The advantage of preserving the PCL remnants was stressed out in two studies. Both Ahn *et al*[32] and Zhao *et al*[66] reported a preserving reconstruction method for chronic, however PCL injuries. The only study available to describe the results of remnant-preserving PCL reconstruction in the acute and sub-acute stage was presented by Jung *et al*[31] but the authors have included patients in the sub-acute phase (3 mo post-injury). They also used hamstrings grafts, which require protection in the early postoperative period. Recently various reports have published good results after PCL reconstruction using LARS artificial ligaments[19,37]. However only in one study the operation was performed in an early stage[19] and the follow-up was relatively short (less than 5 years), which is considered a limitation when artificial grafts are used, because of their tendency to fail in a later phase[15,16].

Despite our efforts, there are limitations in our study. It is a retrospective study, but the majority of similar studies are also retrospective, since the incidence of these injuries is very rare. A second limitation is the sample size, which seems rather small, however it is considered a homogenous sample, since we used a standardized protocol regarding the timing of surgery and the treatment method. We have also excluded patients with vascular injuries, which require different treatment protocol and they also have different prognosis. The follow-up was long enough, compared to other similar studies, reported in the literature. Therefore, we believe that our proposed treatment protocol to treat complex knee injuries, operating in an early fashion and reconstructing PCL with LARS artificial ligament may restore knee stability and provide satisfactory long term clinical outcome.

ARTICLE HIGHLIGHTS

Research background

Complex knee injuries pose a difficult problem across the literature in terms of diagnostic classification while the treatment remains controversial. In particular, there is conflict regarding: (1) Their classification (as benign knee dislocations with intact neurovascular status and knee dislocations with arterial injury are not well classified); (2) their postoperative rehabilitation (as knee dislocations with arterial injury require a period of knee immobilization, whereas "benign" knee dislocations can be treated with aggressive postoperative rehabilitation); (3) the timing of the operation; (4) the graft type; and (5) the lack of long term follow-up. In our study we have tried to address all these issues, because we present a homogenous sample, with a long-term follow-up, using LARS artificial ligament to reconstruct PCL and all patients had the operations in the acute phase. Therefore, we feel that the results presented here are reliable since our study, although retrospective has a clear and robust methodology.

Research motivation

In medicine and in any other research processes, the researcher first he observes a phenomenon, secondly he tries to explain it with a theory, and lastly, he has to reproduce it, to confirm the theory. Taking this into account, we have observed that early reconstruction of these injuries provide better outcomes, because the injured soft tissues, have a better healing potential in the acute phase. There is also always a fear for knee arthrofibrosis, when operating early these injuries; we have therefore, allowed (in all our cases) the inflammation to settle down with the help of intensive physiotherapy after the injury. The artificial ligament also provides the scaffold, necessary for the tissue healing in the appropriate position. Furthermore, it allows early rehabilitation because primary stability is achieved during the operation and no need for further protection is needed during the early postoperative period. The satisfactory outcome after this study's long-term follow-up is supporting the theory of early intervention following our treatment protocol.

Research objectives

The main objective of our study was to present a standard treatment protocol to manage complex knee injuries, taking into account parameters which have not been clearly elaborated in previous studies, such as postoperative rehabilitation, timing of the operation, follow-up *etc*. The various parameters of the protocol have been well defined and we suggest this protocol, since we have found very promising outcomes for our patient sample.

Research methods

In this retrospective study, we have used a range of clinical outcome measures and radiological parameters. Clinical measures included three knee-specific measures; the Knee Outcome Survey for Activities of Daily Living (KOS-ADLS), the Lysholm scale, the Knee Osteoarthritis Outcome Survey (KOOS) as well as a generic health measure, the SF-12 Health Survey, all of which present as the most commonly used self-reported outcomes in similar type of studies. In addition, for detecting any anteroposterior (AP) instability we have used the Telos devise. We have also used plain radiographs to detect any possible remaining instability and post-traumatic arthritis. However, we believe that the main advantages of our methodology is (1) Our homogenous sample selection (not including patients with vascular injury or major fracture around the knee); (2) the fact that the sample were all treated with the same standardized protocol; and (3) that postoperative rehabilitation was also intensive with no serious precautions regarding sophisticated and expensive braces.

Research results

Authors study we have found satisfactory clinical outcomes after a long period of time. The functional scores, which have been used in our study yielded very good results. The remaining instability was minimal in most cases and the rate of posttraumatic arthritis was not detectable in most of our cases, given the long follow-up. In future, we may have to include an MRI to detect any occult meniscal or cartilage injuries.

Research conclusions

The new findings of this study support the theory of early intervention following

complex knee injuries (without concomitant serious vascular or bony injuries) as clinical, functional and radiological outcomes have all been satisfactory during our long follow-up. We propose to treat early these injuries, providing that the patient has achieved a good range of motion preoperatively. We also suggest augmenting PCL remnants with LARS artificial ligament, which has been proven adequate in the long-term follow-up. In summary, the proposed treatment protocol is efficient in complex knee injuries, providing there is no concomitant serious vascular or bony injuries. The new hypothesis proposed by this study is the reconstruction of complex knee injuries in the acute phase. The cornerstone of our approach is to start early intensive physiotherapy, to operate as soon as the inflammation settles down and to repair all tissues in one stage. We augment the PCL with LARS artificial ligament and we also augment the repair of collateral ligaments. Based on these findings, we feel that all these injuries should be treated in the acute phase. The new methods are the use of LARS artificial ligament, only for PCL reconstruction and the repair of all the injuries in one stage. With this approach the patients may return earlier to their previous functional level. We feel that this is a major achievement because these injuries may be disabling when they are not treated appropriately.

Research perspectives

The experience learnt from this study was to proceed for proper classification of complex knee injuries. We cannot classify them all in the same category since the prognosis and the treatment protocol is different in injuries complicated with vascular or serious bony injuries. The direction of the future research should be oriented towards the better classification of these injuries and to determine the use of the various available grafts. The methods for future research, is either biomechanical or clinical. The problem with clinical studies, is the rarity of the injury, therefore multicenter studies are required.

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ORIGINAL ARTICLE

Retrospective Study

Neglected traumatic hip dislocation: Influence of the increased intracapsular pressure

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Abstract

AIM

To investigate that the increased intracapsular pressure, during the delay period, can interrupt the blood flow to the femoral head.

METHODS

An observational retrospective study included a group of 17 patients with traumatic hip dislocation, their ages at time of injury averaged 26 (range from 3 to 70) years. Outcomes were assessed clinically and radiographically at a period averaged 11.5 (range from 4 to 20) years.

RESULTS

Minor trauma caused dislocation in seven and severe trauma in ten patients. All dislocations were posterior, six isolated dislocation and 11 were associated with other injuries. The negligence period averaged 2.5 (ranged from 1 to 4) d. At the latest visit, the radiography revealed normal hip in 11 and avascular necrosis (AVN) in six patients. Clinically, eight patients were rated as excellent, three good, three fair and three poor.

CONCLUSION

We believe the factors that contribute to increased intracapsular pressure also increase the influence of delayed reduction toward the development of AVN.

Key words: Avascular necrosis; Intracapsular pressure; Traumatic hip dislocation; Delayed reduction

Core tip: Factors influencing outcomes of traumatic hip dislocation include reduction time, the severity of trauma, patients' ages and direction of dislocation. Although these factors have been thoroughly investigated, any of them was not assigned as the causative for the development of the avascular necrosis (AVN). Does the increased intracapsular pressure is the foremost factor? We believe that the factors as hemarthrosis, the position of the limb during the pre-reduction period particularly in posterior dislocation and traction in post-reduction period can increase the intracapsular pressure to a level sufficient for occlusion of intracapsular blood vessels. Delayed reduction accentuates influence of increased intracapsular pressure in favour of the development of AVN.

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INTRODUCTION

As the hip is an inherently stable joint, a substantial force is required for its dislocation. Therefore, associated injuries must be sought[1,2]. However, some biological factors can predispose to dislocation even with minor trauma, for instance, increased the head-shaft angle and diminished or increased femoral torsion[3-5]. In children, hip dislocates mostly after relatively trivial accidents such as slipping or tripping[2,6]. Consequently, the associated injuries are uncommon. The prominence of the associated injury or insignificance of the causative trauma leads to the negligence of hip dislocation[6,7].

There is almost a consensus regarding the prompt reduction of the dislocated hip in order to minimize the incidence of avascular necrosis (AVN)[6-9]. However, an experimental study reported that the reduction time did not consider a critical factor in the appearance of AVN[10].

Effusion of the hip joint was detected with traumatic dislocation at about 35 d post injury[11]. The effusion increases the intracapsular pressure to a level sufficient for tamponade of the retinacular blood vessels[2,11,12]. Likewise, placement of the injured limb in the particular positions during the pre and/or post-reduction periods can tighten the capsule, which increases the intracapsular pressure[13-15]. These reasons explain why some authors noted AVN despite early reduction[6,9].

Over a period of twenty-year, we observed a group of patients with missed traumatic hip dislocations. Although all hips were reduced late and received the same post reduction management, however, only about 35% developed AVN. Therefore, we hypothesized that the delayed reduction is not only the direct factor that contributes to the development of AVN. However, the factors that increase intracapsular pressure may play an important role in the development of AVN.

In order to investigate our hypothesis, we present this study using the patients' records as a source of the outcomes.

MATERIALS AND METHODS

Between February 1993 and March 2013, we have observed and followed a group of 17 patients with a neglected traumatic hip dislocation. Local Ethics Committee approved this retrospective study. Patients were not required to give informed consent to the study because the analysis used anonymous clinical data. The included patients are seven females and ten males their ages at time of injury averaged 26 (range from 3 to 70) years. Baseline details are listed in Table 1. The causative trauma was graded into minor trauma as running, tripping or falling and severe trauma as high-energy impact, crushing, excessive speed (cycling) or excessive force (football)[7]. Dislocation was classified according to the direction into anterior, posterior and central. Then the posterior dislocation was classified according to the Thompson-Epstein classification system[16]. Additionally, dislocation was classified as an isolated or associated with other injuries, which were then classified into polytrauma, or injuries related to the dislocated side as sciatic nerve injury, femoral fractures or knee injuries. Negligence period was estimated from time of the trauma to the time of the certain reduction.

All dislocations were reduced closed and received the same post reduction management, which consists of aspiration of the hip joint, skin or skeletal traction for three weeks followed by another three weeks of non-weight bearing. In case of the dislocations associated with fractures, full weight bearing was allowed when the fractures healed.

Follow-up reviews were undertaken at every other week for 6 wk, and then at three, six and twelve months. After first year, patients were re-evaluated twice per year for 3 years, and then they invited once per year. The follow-up period averaged 11.5 (range from 4 to 20) years.

Outcome measures

Radiological assessment: In order to assess the stability of reduction, plain radiography was repeated every other week for 6 wk. Development of AVN was assessed every 6 mo for 3 years and then once per year. AVN was defined as the appearance of subchondral sclerosis or the presence of segmental collapse. Associated fractures were considered during the follow-up visits.

Clinical assessment: Clinical outcome was evaluated according to Matta clinical evaluation system[17] that evaluates with points the pain, walking and range of hip

Table 1 Baseline data and outcome for a group of patients, they were treated late for traumatic hip dislocation

No.	Baseline data						Outcomes			
	Age	Sex	NP in days	Trauma	Dislocation type	Associated injury	Follow-up period, yr	Clinical		Radiologic
								Score	Rating	
1	3	M	4	Minor	T-E type 1	Isolated	20	18 point	Excellent	Normal
2	33	M	3	Severe	T-E type 1	Polytrauma	18	14 point	Fair	AVN
3	5	F	3	Minor	T-E type 1	Isolated	18	18 point	Excellent	Normal
4	27	M	2	Severe	T-E type 1	Polytrauma	16	12 point	Poor	AVN
5	55	M	1	Severe	T-E type 4	Polytrauma	15	14 point	Fair	AVN
6	26	M	1	Severe	T-E type 2	Acetabular fracture	15	16 point	Good	Normal
7	19	M	2	Severe	T-E type 3	Acetabular fracture	13	14 point	Fair	AVN
8	6	F	2	Minor	T-E type 1	Isolated	12	18 point	Excellent	Normal
9	4	M	3	Minor	T-E type 1	Sciatic	12	18 point	Excellent	Normal
10	70	F	3	Minor	T-E type 1	Isolated	9	18 point	Excellent	Normal
11	36	F	4	Severe	T-E type 4	Polytrauma	8	12 point	Poor	AVN
12	4	F	3	Minor	T-E type 1	Isolated	8	18 point	Excellent	Normal
13	36	M	2	Severe	T-E type 2	Acetabular fracture	8	17 point	Good	Normal
14	24	F	2	Severe	T-E type 2	Acetabular fracture	7	16 point	Good	Normal
15	6	F	2	Severe	T-E type 1	Femoral fracture	7	18 point	Excellent	Normal
16	29	M	4	Severe	T-E type 1	Polytrauma	6	12 point	Poor	AVN
17	57	M	1	Minor	T-E type 1	Isolated	4	18 point	Excellent	Normal

NP: Negligence period; M: Male; F: Female; T-E: Thompson-Epstein; AVN: Avascular necrosis.

motion. The clinical scores were classified as excellent = 18 points, good = 15-17 points, fair = 13-14 points and poor ⩽ 13 points[17].

RESULTS

The causative trauma was classified as minor in seven cases and severe trauma in ten cases. The direction of the hip dislocations was posterior in all cases. According to the Thompson-Epstein classification system[16], 11 cases were classified as a type 1, three cases type 2, one case type 3, and two cases type 4. Six cases were classified as isolated dislocation and 11 cases were associated with other injuries (Table 1). The negligence period averaged 2.5 (ranged from 1 to 4) d.

Post-reduction aspiration of the hip joints revealed hemarthrosis in six, synovial fluid in four, and negative aspiration in seven hip joints.

Radiographic outcome

The normal appearance of the femoral head compared to the contralateral side was observed in 11 patients and AVN signs were observed in six patients.

Clinical outcome

According to Matta[17] eight patients were rated as excellent, three good, three fair and three poor (Table 1). The overall rating was good and the overall score averaged 16 (ranged from 12 to 18) points. No general complication was reported, the associated fractures healed in the accepted position and the injured sciatic nerve cured.

We have noticed a relationship between the patients' ages and severity of the trauma on one hand and the outcomes on the other hand. Five patients with an average age of 4.4 years (range from 3-6 years) had hip dislocation due to minor trauma achieved excellent outcomes as well signs of AVN were not detected during the follow-up period. Similarly, a female patient 6-years old, although had dislocation due to severe trauma, however, has an excellent result with no AVN. Conversely, the patients who developed AVN their ages averaged 33 years (range: 19 to 55 years), had exposed to severe trauma and the post-reduction aspiration of the hip joints revealed hemarthrosis.

DISCUSSION

Factors influencing outcomes of traumatic hip dislocation include reduction time, severity of trauma, patients' ages and direction of dislocation. Although these factors have been thoroughly investigated, any of them was not assigned as the causative for the development of the AVN. Does the increased intracapsular pressure is the foremost factor?

Diagnosis of traumatic hip dislocation is easy, many authors and we likewise have noticed missed cases. Prominence of the associated injuries or insignificance of the trauma really leads to delay of the diagnosis[6,7]. Although delayed reduction has been regularly linked to incidence of AVN, definition of negligence period is not clear in the literature[1,9]. Experimentally, AVN was produced in the capital femoral epiphysis of immature dogs after increasing the intracapsular pressure for six hours and in the adult dogs for 12 h[18,19]. Consequently, dislocation is considered neglected when the reduction was not achieved before 12 h of injury. In the present study, all cases were reduced at an average 2.5 d, only 35% of the cases developed AVN (Table 1). Sapkas *et al*[10] have considered the reduction time is not a critical factor in the appearance of AVN.

Minor trauma can dislocate the hip in children (Figure 1), likewise at any age in the presence of the biological predisposing factors[2-5]. Thus, it is not mostly

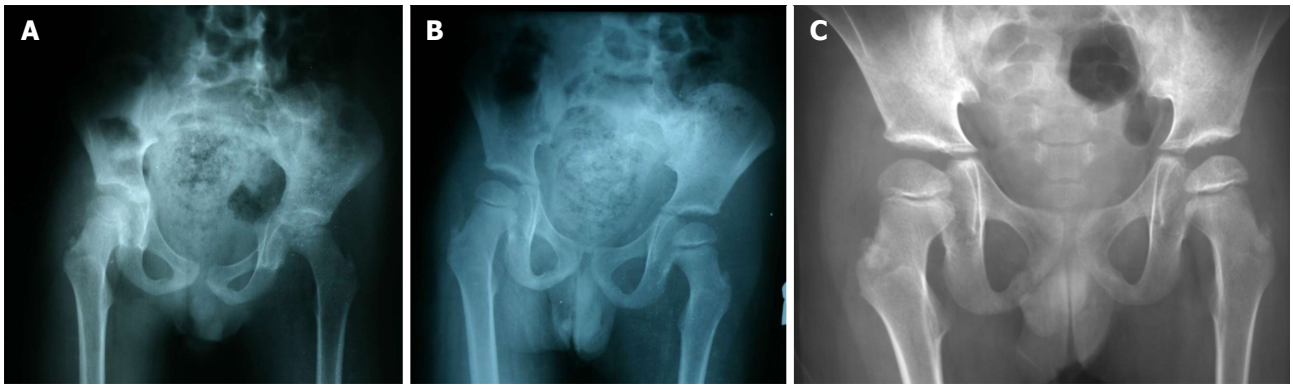

Figure 1 Plain radiographs of the pelvis both hip joints for a 4-year-old boy; the right hip joint was dislocated after minor trauma. A: Notice the neck-shaft angle; B: A radiograph was taken one week after closed reduction shows the stable reduction; C: A radiograph was taken after three years of reduction shows no signs of avascular necrosis.

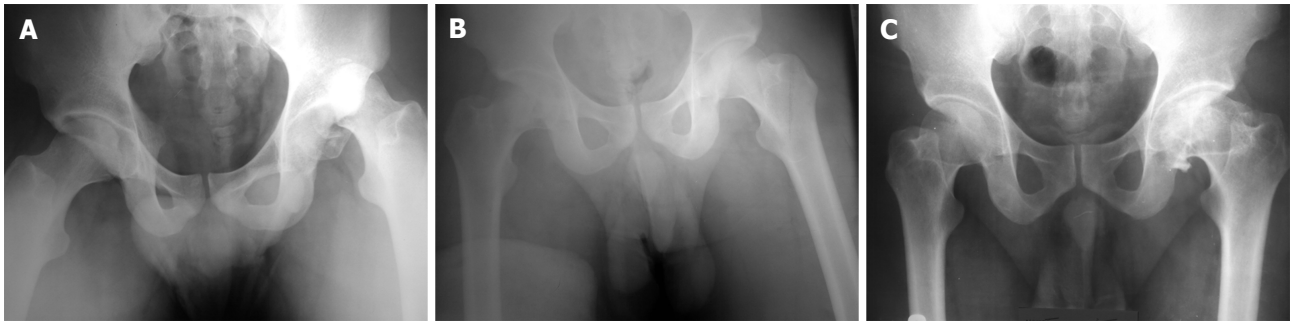

Figure 2 Plain radiographs of the pelvis both hip joints for a 27-year-old male, was admitted to hospital as a polytraumatized patient, the right hip dislocation was reduced two days after injury. A: The right hip dislocated posteriorly; B: Stable reduction by the second month; C: A radiograph was taken 16 years after reduction shows avascular necrosis of the femoral head and degenerative changes of the right hip joint.

associated with other injuries[6-8]. However, severe trauma at least associated with a hemarthrosis. Laorr *et al*[11], investigated 18 patients with traumatic hip dislocation and found hemarthrosis in all cases. This explains why many authors have linked severity of trauma to the incidence of AVN[7,10,20]. In the present study, we detected hemarthrosis in six, synovial fluid in four, and negative aspiration in seven hip joints. Additionally, the hips that were dislocated due to minor trauma have normal femoral heads, while most of those had dislocations due to severe trauma developed AVN during the follow-up period (Figures 1 and 2). However, the dislocations that associated with acetabular (Figure 3) or femoral shaft fractures have not developed AVN (cases No. 6, 13, 14 and 15 in Table 1). The associated femoral fractures, likely resulted from a substantial force sufficient for laceration of the hip capsule additionally[1]. Any of acetabular fracture or capsular laceration allowed for leakage of the hemarthrosis, and therefore, the intracapsular pressure has not increased.

The patient's age can predict the outcomes through the severity of trauma on the one hand and the age-related changes of the femoral head circulation on the other hand. At age under 5 years, the acetabulum is primarily soft pliable cartilage as well as there is a generalized ligamentous laxity, therefore the minor trauma can dislocate the hip joint[2,6]. Additionally, it has been reported that the variations in the age-related sequelae of the traumatic hip dislocation have been in part attributed to the age-related changes in the hip circulation[2,8,12,21].

At the fourth year of age, the femoral head is supplied through a retinacular arterial system, which consists of multiple arteries. With age, the multiple small vessels of the young coalesce to a limited number of larger vessels. Thus, damage to a single blood vessel can have serious consequences[2]. Most authors suggest that the posterosuperior branch of the medial circumflex artery is the most likely site of vascular damage[10,21,22]. Nevertheless, such vessels have a more ability to accommodate the extreme posterior displacement of the femoral head[23]. This explains why many authors have reported the continuation of femoral head circulation after reduction of pure hip dislocation[8,22].

Direction of hip dislocation plays an important role in the development of AVN[8]. Generally, pure anterior dislocations have a better long-term prognosis than posterior dislocations[1,20]. In anterior dislocations, the capsule is disrupted anteriorly and inferiorly while in posterior dislocations the capsular tear either inferoposterior or directly posterior, depending on the amount of flexion present[1]. As the posterosuperior vessels is the most likely site of vascular damage[10,21,22], the posteriorly dislocated femoral head compress

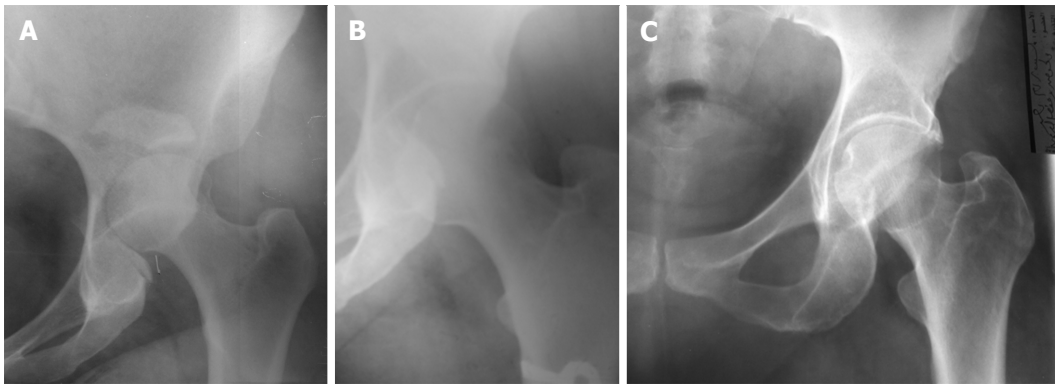

Figure 3 Plain radiographs of right hip joint for a 42-year-old female, was diagnosed two days after a motor car accident. A: A posterior dislocation of the right hip with acetabular fractures; B: A radiograph was taken two weeks after closed reduction shows stable reduction; C: A radiograph was taken seven years after reduction shows no signs of avascular necrosis in the head of right femur.

these vessels against the posterior acetabular rim and interrupt the femoral head circulation[22]. Position of the limb prior to reduction also plays a role in the development of AVN[13]. In posterior dislocations, the leg is flexed, adducted, and internally rotated while in anterior dislocations, the leg is externally rotated with varying amounts of flexion and abduction[1]. So, the deformity in anterior dislocation increases capacity of the hip capsule to accommodate pressure more than that in posterior dislocation[13-15]. Moreover, recognizable limb deformity in anterior dislocation renders negligence is less likely.

Hip joint is enclosed by a thick fibrous capsule[2]. Therefore, the trauma that has sufficient severity to dislocate the inherently stable joint, constantly results in hemarthrosis, which increases the intracapsular pressure to a level sufficient to tamponade of the retinacular blood vessels[2,11,12]. This was proved experimentally in two separate studies, as they produced AVN when the intracapsular pressure of the hip was increased for six or twelve hours[18,19]. Likewise, the tight repair of the hip capsule after surgical dislocation led to a drop in the perfusion of the femoral head[20,22]. Given that, the development of AVN must depend essentially upon the steadiness of interruption of blood flow[21]. Hence, the hemarthrosis that was detected at an average 13.2 d after injury will offer the circumstance sufficient for the development of avascular AVN even after prompt reduction[11,12].

Post reduction management plays a role in the development of AVN. Most surgeons recommend a period of traction until the patient's initial pain has subsided. However, this position increases the intracapsular pressure[13-15,20,21]. Therefore, the best recommendations for post-reduction treatment are avoidance of strict immobilization and allow full weight bearing once the patient can control his leg in space[1,11-13]. Aspiration of the hip, if it has hemarthrosis, should be repeated during the first day and in the next days as long as the joint effusion persists.

The present study has many limitations: In part, the included data were retrospectively collected from a heterogeneous group of patients and in another part, lacked the use of the diagnostic tools as measuring of intracapsular pressure and MRI. However, heterogeneity provided an opportunity for studying of different age groups and different types of trauma, albeit in a small number of patients. Availability of patients for a considerable period of follow-up offered the data that warranted the building of the logical opinion.

We believe that the factors as hemarthrosis, the position of the limb during the pre-reduction period particularly in posterior dislocation and traction in post-reduction period can increase the intracapsular pressure to a level sufficient for occlusion of intracapsular blood vessels. Delayed reduction accentuates influence of increased intracapsular pressure in favour of the development of AVN.

ARTICLE HIGHLIGHTS

Research background

In February 1993, a 3-years old boy present with the secondary inability to walk after fall during running since four days. Hip dislocation was detected and reduced immediately. In June 1995, a male 33-years-old had present with multiple traumas due to a motor car accident and a hip dislocation that was missed for three days. By the sixth-month post reduction, the second patient developed avascular necrosis (AVN). In the same week, I called the first patient for follow-up and radiological examination that revealed normal hips. At this moment I wondered, why the second patient developed AVN despite the delayed reduction was the common denominator? In subsequent years I started a study titled "Fixation of intracapsular femoral neck fractures: Effect of trans-osseous capsular decompression" (published). Therefore, the importance of the intracapsular pressure has resurfaced. Again I wondered, what the relationship between the age and the severity of the trauma regarding the hip dislocation? As well, what the influence of hemarthrosis on the development of AVN?

Research motivation

This study was conducted for answering of the inquiries that can be summarized in, "when we expect the development of the AVN after hip dislocation and how to avoid the predisposing factors".

Research objectives

The objective of this study was the detection of the factor(s) that can accentuate hazardous of delayed reduction. We assumed increased intracapsular pressure is the concerned factor. Realizing this hypothesis will open the way for avoidance the complications resulted from hip joint effusion either due to

trauma or disease.

Research methods
This is an observational retrospective study depend on the analysis of patients records and reviewing of the literature in realizing of its objectives.

Research results
We have noticed a relationship between the patients' ages and severity of the trauma regarding the incidence of the hip dislocation, as well the severity of trauma and development of AVN.

Research conclusions
Increased intracapsular pressure can be a result of the combined effect of hip dislocation and traction of the limb in the post-reduction period. Complications of hip diseases that associated with hip effusion as infections or Perthes disease can be diminished through reduction of intracapsular pressure. The prompt reduction is not enough to avoid the development of the AVN. The interferences as traction of the limb for immobilization can increase the intracapsular pressure of hip joint. Influence of the intracapsular pressure varies according to the patient's age. I suggest a prospective study using the advanced instruments for prediction of the development of AVN. The associated acetabular fractures allowed leakage of the hemarthrosis as well fracture of femoral shaft possibly lacerated the hip capsule and in both cases, we could not detect fluid through aspiration. The recommendations for post-reduction treatment are the aspiration of the hemarthrosis, avoidance of strict immobilization and allow full weight bearing once the patient can control his leg in space.

Research perspectives
Despite the heterogeneity of the patients, however, it provided an opportunity for studying of different age groups and different types of trauma, albeit in a small number of patients. The future research should be directed toward the reduction of the complications of the diseases that associated with increased of the intracapsular pressure. The best method for the future research is a prospective randomized controlled study.

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ORIGINAL ARTICLE

Clinical Practice Study

Establishing minimum clinically important difference values for the Patient-Reported Outcomes Measurement Information System Physical Function, hip disability and osteoarthritis outcome score for joint reconstruction, and knee injury and osteoarthritis outcome score for joint reconstruction in orthopaedics

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Author contributions: Hung M was instrumental in study design, data collection, data processing, data analysis, interpretation, study oversight, literature review, manuscript writing and editing; Bounsanga J was instrumental in data processing, data analysis, manuscript writing and editing; Voss MW was instrumental in literature review, data analysis, manuscript writing and editing; Saltzman CL was instrumental in study design, data collection, interpretation and manuscript editing.

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Abstract

AIM

To establish minimum clinically important difference (MCID) for measurements in an orthopaedic patient population with joint disorders.

METHODS

Adult patients aged 18 years and older seeking care for joint conditions at an orthopaedic clinic took the Patient-Reported Outcomes Measurement Information System Physical Function (PROMIS® PF) computerized adaptive test (CAT), hip disability and osteoarthritis outcome score for joint reconstruction (HOOS JR), and the knee injury and osteoarthritis outcome score for joint reconstruction (KOOS JR) from February 2014 to April 2017. MCIDs were calculated using anchor-based and distribution-based methods. Patient reports of meaningful change in function since their first clinic encounter were used as an anchor.

RESULTS

There were 2226 patients who participated with a mean age of 61.16 (SD = 12.84) years, 41.6% male, and 89.7% Caucasian. Mean change ranged from 7.29 to 8.41 for the PROMIS® PF CAT, from 14.81 to 19.68 for the HOOS JR, and from 14.51 to 18.85 for the KOOS JR. ROC cut-offs ranged from 1.97-8.18 for the PF CAT, 6.33-43.36 for the HOOS JR, and 2.21-8.16 for the KOOS JR. Distribution-based methods estimated MCID values ranging from 2.45 to 21.55 for the PROMIS® PF CAT; from 3.90 to 43.61 for the HOOS JR, and from 3.98 to 40.67 for the KOOS JR. The median MCID value in the range was similar to the mean change score for each measure and was 7.9 for the PF CAT, 18.0 for the HOOS JR, and 15.1 for the KOOS JR.

CONCLUSION

This is the first comprehensive study providing a wide range of MCIDs for the PROMIS® PF, HOOS JR, and KOOS JR in orthopaedic patients with joint ailments.

Key words: Hhip disability and osteoarthritis outcome score for joint reconstruction; Patient-Reported Outcomes Measurement Information System Physical Function; Knee injury and osteoarthritis outcome score for joint reconstruction; Minimum clinically important difference; Joint; Physical function; Minimum detectable change; Arthroplasty; Orthopaedics; Clinical outcomes

Core tip: Personal value judgments should be used to apply these minimum clinically important difference (MCID) values to treatment planning and in guiding patient expectations of change. We recommend applying low values of MCIDs for screening purposes and median values as a more conservative cut-off for evaluating longitudinal change.

Hung M, Bounsanga J, Voss MW, Saltzman CL. Establishing minimum clinically important difference values for the Patient-Reported Outcomes Measurement Information System Physical Function, hip disability and osteoarthritis outcome score for joint reconstruction, and knee injury and osteoarthritis outcome score for joint reconstruction in orthopaedics. *World J Orthop* 2018; 9(3): 41-49 Available from: URL: http://www.wjgnet.com/2218-5836/full/v9/i3/41.htm DOI: http://dx.doi.org/10.5312/wjo.v9.i3.41

INTRODUCTION

The National Institutes of Health sponsored an initiative to develop a Patient-Reported Outcomes Measurement Information System (PROMIS®)[1] using item response theory (IRT) methods. These methods have been recommended for use in the evaluation of arthroplasty outcomes because of their unique measurement properties[2]. Computerized adaptive testing (CAT) using IRT minimizes respondent burden without sacrificing instrument precision[3,4]. The PROMIS® Physical Function (PF) CAT assesses physical function in five domains but is not directly targeted at joint function. Yet the useful measurement and administration qualities of the PROMIS® PF CAT make it a valuable addition to patient-reported outcomes (PRO) assessments in joint reconstruction[5,6]. Aside from minimizing burden, top quality PRO instruments also offer reliable and valid scores that are easy to interpret[7].

Recent attention in PRO development has focused in on the interpretability of scores, particularly in terms of how meaningful the outcomes are to patients[8]. Change in function is an important clinical outcome, thus PROs should be able to detect change in patient function. In interpreting change, the minimum clinically important difference (MCID) reflects the smallest amount of meaningful change[9]. "MCIDs are patient derived scores that reflect changes in a clinical intervention that are meaningful for the patient"[10]. Meaningful change is important, as it can serve as a benchmark of treatment effect, and it is critical in decision making. Whether or not a treatment produces a statistically significant outcome is less informative than whether it produces meaningful change, as an inflated sample size can yield statistical significance without clinical relevance[11,12].

Multiple methods have been developed for determining MCID values and there is little agreement on the best standard to apply[10]. Distribution-based approaches rely on statistical methods and probability sampling. They describe how much change falls beyond random levels of variation. They rely on distributions of scores and how much the scores vary between patients in reaching a magnitude of change that is beyond chance fluctuation[13]. But distribution methods cannot

tell us whether the amount of change is meaningful from the clinician's or the patient's perspective[8]. An alternative approach is to use anchor-based methods which relates the change in patient scores to some other measure of health outcomes[13].

Determining the MCID of the PROMIS® PF is an important step to understand the meaning of the scores. Collecting the longitudinal data necessary to analyze meaningful change takes time. Because the PROMIS® development began quite recently in 2004[1], there have been very few studies estimating MCIDs for PROMIS® measures and little is known about MCID values in the orthopaedic adult reconstruction population[14]. Initial MCID development for PROMIS® instruments has begun in specific patient populations such as pediatrics[15] or cancer patients[16] but studies are lacking in orthopaedic patients.

Other PROs have been developed that are specific to the domain of joint function and it is helpful to consider the measurement properties of these newer instruments side by side. The knee injury and osteoarthritis outcome score for joint reconstruction (KOOS JR) and the hip disability and osteoarthritis outcome score for joint reconstruction (HOOS JR) are two joint specific instruments recently introduced in the arthroplasty arena[17-20]. Both instruments have been approved by the Centers for Medicaid and Medicare Services for use in joint replacement registries[21-24]. The HOOS and KOOS were selected given their use in joint replacement registries in the United States, though other valid measures such as the Oxford hip or knee score are more common in European registries and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) has a longer-term use for more general assessments of osteoarthritis[21]. Prior research has demonstrated that the HOOS and KOOS measures are sensitive to change[25]; however, we are unaware of any studies that develop MCIDs for these instruments[26]. The purpose of this study was to determine the MCIDs of the PROMIS® PF CAT, the HOOS JR, and the KOOS JR in an orthopaedic population with lower-extremity joint conditions.

MATERIALS AND METHODS

Patient sample

After receiving approval from the University of Utah Institutional Review Board, we analyzed data from an adult reconstruction population at a single academic medical center. All patients, aged 18 and older with pathology of the hip and knee were eligible for inclusion. As part of the standard of care, patients were provided with internet enabled hand-held tablets to answer demographic and PRO instruments which are linked to the electronic health record system *via* mEval. Questionnaires were either completed at clinic check-in or within 7-d prior to their visit *via* email. Follow-up data were obtained in the same manner at future clinic visits. No informed consent was obtained as all PRO measurement was conducted as a part of customary standard of care. For this study, these visits were organized into four follow-up periods based upon the first recorded score within the database (baseline initial assessment): (1) 3-mo follow-up (80 to 100 d after initial assessment); (2) > 3-mo follow-up (90 d or more after initial assessment); 6-mo follow-up (170 to 190 d after initial assessment); and (3) > 6-mo follow-up (180 d or more after initial assessment). These follow-up periods were selected based upon recommendations within the literature[27-37]. It should be noted that the baseline score may not necessarily correlate with a specific intervention. Nonetheless, this method still allows for the monitoring of change over time.

A major goal of MCID determination is to allow for meaningful interpretation of scores for clinical decision-making, in addition to sample size calculation for investigating treatment effectiveness. As there is essentially no evidence that MCID values are dependent on the severity of disease conditions, length of follow-ups, or specific patient groups[38-40], it is appropriate for this study to establish MCIDs among orthopaedic patients with a full range of joint impairments and varying follow-up time points. The present evaluation of MCID values was conducted in a general joint clinic population, among surgical and non-surgical patient samples regardless of specific treatment or intervention. Since MCID development were not meant to be treatment specific[40], MCID values derived from this study can be applied to adult reconstruction patients with all types of surgical and non-surgical interventions.

Patient-reported outcomes

The PROMIS® PF CAT, v1.2, draws from a 121-item test bank that contains both upper extremity and lower extremity functional items. The PROMIS® PF CAT algorithms were established by PROMIS® developers[41], and the instrument was scored using T-scores, a standardized metric that has a mean of 50 and a standard deviation of 10[5]. Higher scores on the PROMIS® PF CAT indicate higher physical function.

HOOS JR: The HOOS JR is a 6-item measure assessing function and pain[22] with psychometric properties similar to the full HOOS[42]. The HOOS JR was scored on a 0 - 100 scale with larger numbers indicating higher hip function.

KOOS JR: The KOOS JR is a 7-item measure assessing function and pain[24]. The KOOS JR is scored on a 0-100 scale with larger numbers indicating higher levels of knee function.

Statistical analysis

Descriptive statistics regarding patient characteristics and demographics were calculated. Mean change scores for the patients were evaluated for each time-period. Change scores were calculated as the follow-up score minus the baseline score on each measure, and

Table 1 Demographics of patients (*n* = 2226)

Patient characteristics	*n*	Percent	Mean (SD)	Range
Age (yr)			61.16 (12.84)	18-93
Gender				
Male	927	41.6		
Female	1299	58.4		
Race				
White or Caucasian	1997	89.7		
Black or African American	27	1.2		
Asian	20	0.9		
American Indian and Alaska Native	32	1.4		
Native Hawaiian or Pacific Islander	11	0.5		
Other	113	5.1		
Unknown/missing	26	1.2		
Ethnicity				
Hispanic	114	5.1		
Non-Hispanic	2075	93.2		
Missing	37	1.7		

recorded as the absolute value difference between the scores. They were calculated for each of the follow-up periods described above including 3-mo, > 3 mo, 6-mo, and > 6 mo time-points.

The anchor-based methods applied patients' perspective to the question: "Compared to your FIRST EVALUATION at the University Orthopaedic Center: how would you describe your physical function now?" (much worse, worse, slightly worse, no change, slightly improved, improved, much improved) as a determinant of meaningful change. No change equates to a 0 value; the negative ratings are from -3 to -1 and positive ratings are from 1 to 3. When change is anchored to the patient perception or report of deterioration or improvement, it can be interpreted as a meaningful (or noticeable) level of change[9]. Patients with a ± 2 or ± 3 point change (much worse, worse, improved, much improved) were included in each analysis of change, a method used to distinguish noticeable change from no-change[43,44]. Patients reporting no change or only slight change were considered together as the no-change group. We combined the improved and deteriorated conditions using absolute values of the change scores to distinguish change from stable symptomology[45].

The distribution-based methods included calculations based on the standard deviation (SD) and on the minimum detectable change (MDC). The SD approach used the 1/2 SD and 1/3 SD as variation-based estimates of MCID. The MDC is based on the standard error of measurement (SEM) of the follow-up scores and is the smallest score change that likely reflects a true change in condition. We calculated MDC at three confidence levels: 90%, 95% and 99%. The formulas for calculating the MDC are: $MDC_{@90\%} = 1.65 * 2^{1/2} * SEM$; $MDC_{@95\%} = 1.96 * 2^{1/2} * SEM$; $MDC_{@99\%} = 2.56 * 2^{1/2} * SEM$. The SEM equals to $SD*(1-r)^{1/2}$, where r is the reliability represented by Cronbach alpha and SD is the standard deviation of the follow-up scores.

We fitted the receiver operating curve (ROC) to measure the best cut-off points to maximize sensitivity and specificity of the instruments. The cut-off was calculated as (sensitivity + specificity) -1, based on Youden's J value[46]. Sensitivity is the proportion of correct identification of patients who showed changes, and specificity is the proportion of correct identification of patients showing no meaningful change. All statistical analyses were performed using SPSS 24.0 (IBM SPSS Statistics for Windows, Armonk, NY: IBM Corp.)[47], and R 3.30 (R Development Core Team, Vienna, AT: R Foundation for Statistical Computing)[48].

RESULTS

Demographics

A total of 2226 patients were included in the study. Mean age of participants was 61.16 years (SD = 12.84), with a range of 18-93 years. Most participants in the study were White or Caucasian (89.7%) and Non-Hispanic (93.2%). Detailed demographics can be found in Table 1.

Anchor-based methods

Mean change: Mean change scores varied at each follow-up period. In terms of patients experiencing change, the highest mean change scores were observed at the 6-mo follow-up for the PF CAT (8.41), HOOS JR (19.68), and KOOS JR (18.85). The lowest mean change scores for patients experiencing change was at the 3-mo follow-up for all three measures. For the PF CAT mean change at 3-mo was 7.60 points, for the HOOS JR it was 14.81 points, and for the KOOS JR. It was 14.51 points. The median MCID value from the complete range of all two anchor-based methods and five distribution-based methods analyzed at all four time-points was similar to the mean change score for each measure and was 7.9 for the PF CAT, 18.0 for the HOOS JR, and 15.1 for the KOOS JR (Figure 1).

ROC curve: The ROC area under the curve was used to identify the optimal cut-off point between meaningful and non-meaningful change, by calculating the point at which the sum of false positive and false negative identifications are the fewest[49]. The highest ROC MCID value for the PF CAT was 8.18 at > 6-mo follow-up. For the HOOS JR the highest value was 43.36 observed at the 3-mo follow-up with a small sample size (*n* = 24). For the KOOS JR, the highest MCID value was 8.16 at > 3-mo follow-up. Detailed mean change and ROC cut-off values for the PF CAT, HOOS JR. and KOOS JR. can be found in Table 2.

Distribution-based methods

1/2 standard deviation of each of the function and pain scores: The PF CAT (4.35) had the highest ½ SD value at the > 6-mo follow-up whereas the HOOS

Table 2 Anchor-based methods for minimum clinically important difference determination of the PROMIS PF CAT, HOOS JR and KOOS JR

Instrument	*n*	No change (SD)	*n*	Mean change (SD)	ROC cut-off
3-mo from baseline follow-up					
PF CAT	54	6.95 (6.70)	88	7.60 (4.98)	1.97
HOOS JR	6	22.81 (10.10)	24	14.81 (12.45)	43.36
KOOS JR	14	10.49 (10.00)	37	14.51 (9.76)	7.24
> 3-mo from baseline follow-up					
PF CAT	366	6.02 (5.40)	577	7.29 (7.31)	3.44
HOOS JR	48	14.34 (15.23)	110	18.49 (12.53)	8.07
KOOS JR	96	12.71 (12.62)	151	14.82 (12.56)	8.16
6-mo from baseline follow-up					
PF CAT	21	4.36 (4.32)	34	8.41 (6.12)	3.52
HOOS JR	6	6.62 (5.87)	5	19.68 (18.65)	7.45
KOOS JR	12	13.49 (11.07)	14	18.85 (12.82)	6.12
> 6-mo from baseline follow-up					
PF CAT	192	6.44 (5.83)	421	7.69 (6.75)	8.18
HOOS JR	76	12.58 (11.61)	57	17.57 (13.92)	6.33
KOOS JR	81	12.45 (10.77)	64	15.47 (13.38)	2.21

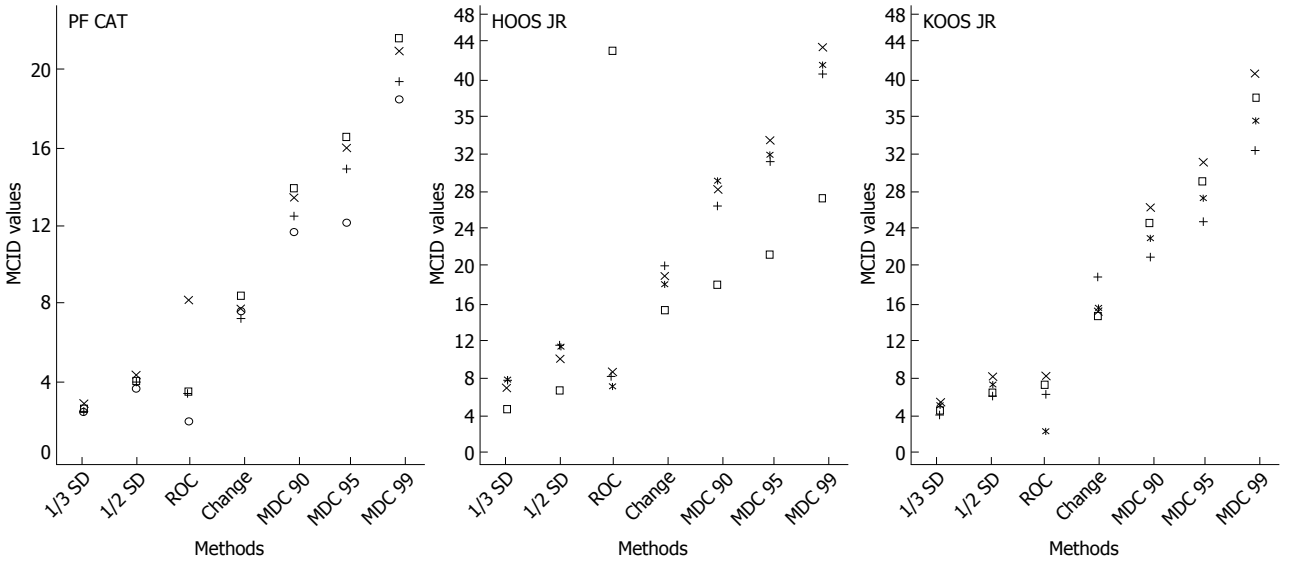

Figure 1 Multi-method minimum clinically important difference score ranges for PROMIS PF CAT, HOOS JR, and KOOS JR.

JR (10.96) had the highest ½ SD value at the 6-mo follow-up. The highest ½ SD value for the KOOS JR was 8.02 at the > 3-mo follow-up. At the 3-mo follow-up, PF CAT and HOOS JR had the lowest ½ SD values of 3.68 and 5.86. The KOOS JR had the lowest ½ SD value of 5.96 at the 6-mo follow-up.

1/3 standard deviation of each of the function and pain scores: The highest 1/3 SD value for the PF CAT (2.90) was observed at the > 6-mo follow-up whereas the HOOS JR (7.30) showed the highest 1/3 SD value at the 6-mo follow-up. The KOOS JR had the highest 1/3 SD value of 5.34 at the > 3-mo follow-up but the lowest 1/3 SD value of 3.98 at the 6-mo follow-up. The lowest 1/3 SD values for both the PF CAT (2.45) and HOOS JR (3.90) were observed at the 3-mo follow-up.

Minimum detectable change (MDC) @90%, @95%, @99%: The MDC was highest for the PF CAT ($MDC_{90\%}$ = 13.89, $MDC_{95\%}$ = 16.50, $MDC_{99\%}$ = 21.55) at the 6-mo follow-up. At the > 6-mo follow-up, the MDC was highest for the HOOS JR ($MDC_{90\%}$ = 28.86, $MDC_{99\%}$ = 41.67) and highest at > 3-mo HOOS JR ($MDC_{95\%}$ = 31.90). The highest MDC for the KOOS JR ($MDC_{90\%}$ = 26.21, $MDC_{95\%}$ = 31.14, $MDC_{99\%}$ = 40.67) was observed at the > 3-mo follow-up (Table 3).

DISCUSSION

Determining the values of MCID for PRO measures enhances the interpretability and utility of the instruments. Determining score changes which reflect meaningful change requires understanding the patient perception of improvement or worsening. Anchor-based methods of determining an MCID tie the change scores to the patient reports of change and supplement the distribution-based methods which focus on precision in scores from a statistical standpoint. The current

Table 3 Distribution-based methods for minimum clinically important difference determination of the PROMIS PF CAT, HOOS JR and KOOS JRKOOS JR

Instrument	*n*	SD		MDC		
		1/2	1/3	90%	95%	99%
3-mo from baseline follow-up						
PF CAT	663	3.68	2.45	11.64	14.14	18.47
HOOS JR	99	5.86	3.9	17.54	20.84	27.22
KOOS JR	129	6.52	4.35	24.49	29.09	37.99
> 3-mo from baseline follow-up						
PF CAT	2133	4.02	2.68	12.47	14.82	19.35
HOOS JR	245	9.33	6.22	28.11	33.39	43.61
KOOS JR	365	8.02	5.34	26.21	31.14	40.67
6-mo from baseline follow-up						
PF CAT	264	3.93	2.62	13.89	16.5	21.55
HOOS JR	31	10.96	7.3	26.36	31.31	40.89
KOOS JR	55	5.96	3.98	20.84	24.75	32.33
> 6-mo from baseline follow-up						
PF CAT	1520	4.35	2.9	13.46	15.98	20.88
HOOS JR	112	10.73	7.15	28.86	31.9	41.67
KOOS JR	154	7.12	4.75	22.91	27.22	35.55

MDC: Minimum detectable change.

comprehensive assessment of MCID values utilized multiple methods of anchor-based and distribution-based estimation.

The PROMIS® PF CAT mean change scores in this population of orthopaedic joint patients ranged from 7.29 to 8.41 depending on follow-up points. The ROC area under the curve ranged from 1.97 to 8.18. Distribution-based methods ranged using the SD method from a low of 2.45 (1/3 SD) to 4.35 (½ SD). The values using the MDC approach produced much larger values from 11.64 ($MDC_{90\%}$) to 21.55 ($MDC_{99\%}$). MCID values vary depending on the type of patient population (*e.g.*, orthopaedic, cancer, pediatric) being evaluated, but overall the MCID values identified with the MDC approach in this study are much higher than the 2-3 point MCID of the PROMIS® mobility subscale identified in a pediatric population[15] or the 4-6 point PROMIS® PF CAT MCID values identified in a cancer population[16].

The larger MCID values in this study could have been obtained for a number of reasons. The values could be population specific, reflecting an underlying difference in functional gain between the orthopaedic adult patient population and the pediatric and cancer patient populations previously studied. However, the most likely explanation is that the MCID value obtained is a reflection of the method used for calculation. Unlike other studies that commonly use just one approach to estimate MCID values, the current study used multiple approaches and multiple time points to arrive at twenty-eight MCID values per instrument, allowing better triangulation of results. This study found a great deal of consistency across the follow-up time-points for any one particular method of calculating MCIDs (Tables 2 and 3), suggesting that the methods were responsible for the variation of the MCID values and that the length of follow-ups was mostly irrelevant. It is important to recognize that this study incorporated a wide array of cut-off standards, ranging from lenient to extremely strict. Since $MDC_{95\%}$ and $MDC_{99\%}$ are extremely strict cut-off standards, it is not surprising that these MCID values are high. None of the research reviewed as background for this study calculated MCIDs using such strict criteria[15,16]. The lowest MCID values derived from this study may be appropriate for screening purposes, but the median value (Figure 1) may be a better estimate of true and meaningful change when applying a conservative standard for evaluating treatment effects or for respondent analyses[50]. The more stringent cut-off standard derived MCID values reported in this study provide more definite assurance that important change has occurred.

The mean change for the HOOS JR ranged from 14.81 to 19.68. The ROC area under the curve ranged from 6.33 to 43.36. The 43.36 value appeared to be an outlier and is not considered a reliable estimate. The SD values ranged from 3.90 (1/3 SD) to 10.96 (½ SD). The MDC method of detecting change yielded a range of MCIDs of 17.54 ($MDC_{90\%}$) to 43.61 ($MDC_{99\%}$). These SD values are consistent with previous research identifying an MCID of 9.1 (1/2 SD method) for the HOOS in an arthroplasty population[51]. The median of the HOOS JR MCIDs was 18.0 and may be an appropriate conservative estimate for evaluating treatment effects.

For the KOOS JR, the mean change ranged from 14.51 to 18.85. The ROC maximized MCID values ranged from 2.21 to 8.16. The SD values ranged from 3.98 (1/3 SD) to 8.02 (½ SD). The MDC method of detecting change yielded a range of MCIDs from 20.84 ($MDC_{90\%}$) to 40.67 ($MDC_{99\%}$). The $MDC_{90\%}$ values reported here are actually lower than previous research on the KOOS JR which produced a range for improved individuals from 28.3 to 35.5[52]. The median KOOS JR MCID was 15.1 in this patient population.

The findings demonstrate that the method used

to estimate MCIDs has a large impact on MCID value determination. The KOOS JR, for example, had a 2 point to 40 point difference in MCID depending on the method used. There is not yet consensus on a standardized approach for establishing MCID[10]. The lack of agreement between MCID values reported in this study, depending on the method used, is consistent with findings in the literature[53]. There have been recommendations that MCID determination should be standardized, but the best methods have not been agreed upon[38]. Until a more standardized method is established, the comprehensive range of MCIDs presented in this study provided much deeper insights than many existing studies. This comprehensive presentation enables patients, clinicians, care-givers and decision makers to be well-positioned in making their judgment call as to which MCID value(s) they should select based on how lenient or strict a standard they would like to set for their patients. It is tempting for clinicians to oversimplify and search for a single fixed MCID value, yet a single MCID value is often unstable[8]. A range of MCID values such as those presented in this study should indeed be considered by clinicians and health care practitioners.

The study may be limited by the type of patients who self-selected to return for follow-up visits, which is a common phenomenon across all orthopaedic and other clinics. Patients returning for longer-term follow-up were generally those experiencing more severe conditions and thus may not reflect the full range of improvement in condition. However, this should not be of much concern, as these patients returning for follow-ups were representative of the ones treated regularly in clinics, rendering the results of this study even more practical for standard orthopaedic practice. MCID value determination is generally not dependent on the severity of condition, thus the shorter-term or longer-term follow-up periods would not have impacted the MCID values, as evidenced from the empirical results of this study. In addition, not every patient in this study completed the outcome measures pre-treatment, thus some change scores may reflect a baseline time-point that was post-intervention. Yet these evaluations still produced meaningful change since longitudinal change over time was the main focus, not necessarily change from a specific time point to another specific time point.

One additional limitation comes from the use of anchor-based questions to determine clinically relevant change. An anchor-based question with a global rating of change measure is subject to recall bias, with some research indicating that reports of change may be more related to the current health status than real change from baseline[10]. Different anchor questions may produce different results as well. Distribution methods also have limitations as they derive MCIDs based on the variance of the data, which might be difficult to interpret. Since all methods have strengths and limitations, it was thus our intention for this study to be comprehensive in nature to cover a variety of approaches, allowing readers to make informed decisions in selecting MCID values based on their personal value judgments as to which target MCID is worthwhile to pursue. Lastly, the demographic characteristics of this sample may not be representative of those in the United States and may affect MCID scores. Future research should investigate MCIDs in a more diverse demographic sample. It should also establish MCIDs linking baseline scores using Rasch methodology to provide deeper insights.

Overall, this study utilized rigorous methodologies to develop a wide range of MCID values for the PROMIS® PF, HOOS JR, and KOOS JR in an orthopaedic sample of patients with joint disorders. As there is no such concept as a correct or incorrect MCID, individual value judgments are necessary to apply MCIDs to treatment planning and in guiding patient expectations of treatment change.

ARTICLE HIGHLIGHTS

Research background

Newly developed patient-reported outcomes have many advantages, but require further studies, including establishing minimum clinically important difference (MCID) values. Determining the MCID for the Patient-Reported Outcomes Measurement Information System Physical Function (PROMIS® PF) will be useful for orthopaedic clinical practice and it is helpful to understand the MCID in the context of previously used measures like the hip disability and osteoarthritis outcome score for joint reconstruction (HOOS JR), and the knee injury and osteoarthritis outcome score for joint reconstruction (KOOS JR), Anchor-based and distribution-based methods can both be used to determine MCID.

Research motivation

New instruments require studies to inform their score interpretation. Because of the lack of consensus on MCID methods, a comprehensive approach was taken, using both anchor- and distribution-based methods at multiple levels of precision and multiple follow-up time points. Cross verification of MCID values using powerful triangulation methods allow researchers and clinicians to understand the complexity of MCID evaluation and conscientiously select the most appropriate one for themselves.

Research objectives

To determine MCIDs for the PROMIS PF, HOOS JR and KOOS JR in a general joint orthopaedic patient population applying comprehensive methods.

Research methods

Consecutively enrolled patients aged 18 and older from a large academic orthopaedic joint clinic completed PROs at their first clinic visit and at follow-up points from 3-mo to 6-mo and beyond. These patients also completed an anchor question that queried how much their physical function had improved since their first clinic visit. They were grouped into change and no-change categories. Anchor-based analyses looked at mean change scores and the receiver operating curve to maximize the best cut-off based on sensitivity and specificity. Distribution-based analyses looked at the standard deviation, and minimum detectable change.

Research results

There were 2226 patients who participated with a mean age of 61.16 (SD = 12.84) years, 41.6% male, and 89.7% Caucasian. Mean change ranged from 7.29 to 8.41 for the PROMIS® PF CAT; from 14.81 to 19.68 for the HOOS JR; and from 14.51 to 18.85 for the KOOS JR. ROC cut-offs ranged from 1.97-8.18 for the PF CAT, 6.33-43.36 for the HOOS JR, and 2.21-8.16 for the KOOS JR. Distribution-based methods estimated MCID values ranging from 2.45 to 21.55 for the PROMIS® PF CAT; from 3.90 to 43.61 for the HOOS JR; and from 3.98 to 40.67 for the KOOS JR. The median MCID value in the range was similar to

the mean change score for each measure and was 7.9 for the PF CAT, 18.0 for the HOOS JR, and 15.1 for the KOOS JR.

Research conclusions

Overall this study identified a large range of MCIDs for the PROMIS® PF, HOOS JR, and KOOS JR in an orthopaedic sample of patients with joint ailments. This range reflects the comprehensive strategies applied to determine MCIDs at varying levels of precision and cut off standards. The range of MCIDs presented in this study can be incorporated into decision making to guide treatment recommendations, compute sample size for research studies and clinical trials, and conduct respondent analyses.

Research perspectives

Decisions on which MCID value to select or which MCID value is useful should be based on an individual's personal value and belief. Future research direction should focus on investigation of MCIDs with a more diverse demographic sample and to link MCIDs with baseline scores using Rasch-based methods.

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ORIGINAL ARTICLE

Clinical Practice Study

Use of ketamine sedation for the management of displaced paediatric forearm fractures

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Author contributions: Wiik AV and Stewart C designed the study; Wiik AV and Stewart C collected the data; Wiik AV, Patel P, Bovis J and Cowper A analysed the results; Wiik AV, Patel P, Bovis J, Cowper A, Pastides PS, Hulme A, Evans S and Stewart C interpreted and wrote the report.

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Informed consent statement: Informed consent was obtained prior to any treatment from the parent or guardian.

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Abstract

AIM

To determine if ketamine sedation is a safe and cost effective way of treating displaced paediatric radial and ulna fractures in the emergency department.

METHODS

Following an agreed interdepartmental protocol, fractures of the radius and ulna (moderately to severely displaced) in children between the age of 2 and 16 years old, presenting within a specified 4 mo period, were manipulated in our paediatric emergency department. Verbal and written consent was obtained prior to procedural sedation to ensure parents were informed and satisfied to have ketamine. A single attempt at manipulation was performed. Pre and post

manipulation radiographs were requested and assessed to ensure adequacy of reduction. Parental satisfaction surveys were collected after the procedure to assess the perceived quality of treatment. After closed reduction and cast immobilisation, patients were then followed-up in the paediatric outpatient fracture clinic and functional outcomes measured prospectively. A cost analysis compared to more formal manipulation under a general anaesthetic was also undertaken.

RESULTS

During the 4 mo period of study, 10 closed, moderate to severely displaced fractures were identified and treated in the paediatric emergency department using our ketamine sedation protocol. These included fractures of the growth plate (3), fractures of both radius and ulna (6) and a single isolated proximal radius fracture. The mean time from administration of ketamine until completion of the moulded plaster was 20 min. The mean time interval from sedation to full recovery was 74 min. We had no cases of unacceptable fracture reduction and no patients required any further manipulation, either in fracture clinic or under a more formal general anaesthetic. There were no serious adverse events in relation to the use of ketamine. Parents, patients and clinicians reported extremely favourable outcomes using this technique. Furthermore, compared to using a manipulation under general anaesthesia, each case performed under ketamine sedation was associated with a saving of £1470, the overall study saving being £14700.

CONCLUSION

Ketamine procedural sedation in the paediatric population is a safe and cost effective method for the treatment of displaced fractures of the radius and ulna, with high parent satisfaction rates.

Key words: Paediatrics; Forearm fractures; Displaced fractures; Ketamine; Salter Harris; Procedural sedation

Core tip: Displaced paediatric forearm fractures can be safely and effectively treated in the emergency department with ketamine procedural sedation.

Wiik AV, Patel P, Bovis J, Cowper A, Pastides PS, Hulme A, Evans S, Stewart C. Use of ketamine sedation for the management of displaced paediatric forearm fractures. *World J Orthop* 2018; 9(3): 50-57 Available from: URL: http://www.wjgnet.com/2218-5836/full/v9/i3/50.htm DOI: http://dx.doi.org/10.5312/wjo.v9.i3.50

INTRODUCTION

Fractures of the radius and ulna account for 18% to 40% of all fractures in children[1,2]. They are the most common childhood fracture presenting to the paediatric emergency department (ED), with population studies suggesting that the incidence is on the rise throughout the world[3,4]. The majority are treated in the ED with closed reduction and immobilisation in a cast or a splint[5,6]. An arc of rotation of 100 degrees, split evenly between pronation and supination is accepted as normal[7]. The goal of treatment is to restore appropriate length and alignment so normal forearm rotation can return after healing[8]. Simple closed reduction and temporary stable immobilisation is the standard of care sought for these fractures as they generally heal well and surgical fixation doesn't come without risk[9]. The provision of closed reduction can be problematic as there are variations in treatment practice as result of hospital resources, local policy and experience[10,11]. Despite this, a safe and optimal level of analgesia should be achieved before manipulation to avoid unnecessary distress to the child and to ensure a favourable outcome[12]. Simple analgesia such as paracetamol and non-steroidal anti-inflammatory drugs, along with intra-nasal opiates and nitrous oxide may be sufficient and have been shown to be an effective treatment in the ED[13]. However formal ED procedural sedation is an attractive alternative as it offers a greater opportunity to deliver the optimal fracture reduction and cast application[11]. Sedation in the ED is particularly helpful if the fracture pattern is unstable and requires complex traction manoeuvres to achieve adequate correction[14]. Providing complete treatment in the ED and avoiding theatres would negate the economic and psychosocial impact on the child and family if they were admitted into hospital[15,16]. It also has been shown to be more cost-effective to society, which is important in times of economic austerity[17].

There are a variety of classes of procedural sedation drugs used in the United Kingdom[18]. The most popular include opiods, benzodiazapines, propofol and ketamine[18]. Ketamine is the only drug that does not routinely interfere with protective airway reflexes and spontaneous respiration[18]. Ketamine is also the most complete agent as it produces amnesia, anxiolysis and profound analgesia[19]. This drug was first used in humans in the 1960[20]. It was used extensively in the Vietnam war in the 1970s for surgical anaesthesia due to its good safety profile[21]. Its widespread application in paediatric procedural sedation was developed in the 1990s following the work of Green *et al*[22,23]. Over the last three decades it has become one of the most widely used sedative agents in the ED[24,25]. It acts as a dissociative agent that non-competitively blocks NDMA receptors[20]. Traditionally the dose required is 1-2 mg/kg, administered *via* slow intravenous infusion and can be combined with opiods and benzodiazepines[24].

The aim of this clinical practice study was to determine if ketamine is a safe and cost effective way of treating displaced fractures of the radius and ulna in children.

MATERIALS AND METHODS

From May to September 2017, we prospectively evaluated

Patient label

Chelsea Children's Hospital

Paediatric Procedural Sedation using Ketamine

Date _____ Time_____ Procedure planned _____

Exclusion criteria (risk evaluation) (1)*	ASA greater than 2 (excludes all unstable systemic illness)	Previous adverse reaction to an anaesthetic
	Age under 18 m	Psychosis, ADHD
	Any airway abnormality	Bowel obstruction
	Acute systemic illness, *i.e.*, sepsis	Abnormal conscious state/risk of raised intracranial pressure
PPS information sheet(2)* discussed with patient/parents		
Fasting	2 h (all intake) yes no (in emergency situations the duty consultant can elect to give ketamine without prior fasting)	
Informed consent obtained yes no	Medication(s) prescribed drawn up	
Staffing identified proceduralist Sedationist Nurse Anaestetist informed (bleep 0400)		
Time out	Verification of patient, family members, staff and PPS equipment (3)*	
During Procedure	PPS to be performed in a quiet environment. Baseline observations taken immediately prior to procedure (BP, RR, HR, SpO2) and every 5 min (except BP) until the patient has returned to baseline (4)*	
Post procedure	Patient returned to baseline activity and verbalisation	
	Observations within normal limits	
	Tolerating oral liquids	
	Post procedural care discussed with family (using the information leaflet)	
Clinical staff		
Print name_____Signature_____Role in PPS_____		
Print name_____Signature_____Role in PPS_____		
Print name_____Signature_____Role in PPS_____		

Figure 1 Paediatric Procedural Sedation using Ketamine.

a new ketamine protocol (Figure 1) for paediatric ED procedural sedation at Chelsea and Westminster Hospital (CWH). All eligible children with significantly displaced or unstable fractures of the radius and ulna who presented to CWH ED during daylight weekday hours that needed closed reduction and moulded casting were included. The service improvement project was registered locally (QIP# LA353) to follow good clinical governance practice guidelines.

Treatment protocol

Following triage all children presenting to CWH ED with a suspected fracture of the radius and ulna undergo orthogonal anterior-posterior and lateral radiography. The radiographs are then screened by an ED doctor or triage nurse; if significant malalignment is identified the on-call orthopaedic registrar is notified. If the fracture is deemed suitable for manipulation using sedation the orthopaedic registrar and paediatric ED specialist explain the procedure to the child and parent/legal guardian. Counselling is given prior to obtaining written consent to ensure that the family is happy with the proposed sedation plan. They are advised that other treatment options are available if they wish. The inclusion criteria is any child below the age of 16 years with a significantly displaced or unstable fracture of the radius and/or ulna. Plain radiographs are demonstrated as examples of the nature of these fractures. Exclusion criteria included open fractures, ASA greater than 2, under 18 mo of age, any airway abnormality, acute systemic illness, previous adverse anaesthetic reactions, raised intracranial pressure, and/or bowel obstruction.

Informed written consent is taken and final neurovascular assessment is documented. The weight of the child is measured before he or she is taken to a quiet room for ketamine sedation and closed reduction. The parent/legal guardian is given the option to stay with the child for support and comfort. The team consists of a paediatrician, a specialist ED trainee/consultant with ketamine sedation experience, and an orthopaedic registrar. Blood pressure, pulse, respiratory rate and oxygen saturation are monitored and recorded. An alert is sent to an anaesthetic consultant that the procedure is about to start in case of serious adverse event (SAE) occurs. A sedation checklist is completed.

To start 1 mg/kg of ketamine is given through a peripheral intravenous cannula normally in the antecubital fossa or dorsum of the hand of the contralateral upper limb. After a period of 3 min the child's vitals are rechecked. If the child appears to be sedated a gentle manipulation is attempted. If they are not adequately sedated, a top-up of 0.5 mg/kg is administered. Manipulation is performed; when the position is deemed to be satisfactory a stockinette is placed over the arm followed

by a thin layer of wool and a complete well moulded cast utilizing three point fixation. The level of the fracture determines the decision whether or not to extend the cast above the elbow.

Generally the child begins to wake after 20 min and is monitored until fully verbalising with normal observations. Radiographs are performed to ensure a satisfactory reduction and compared to the pre-injury images; these are presented at trauma meeting the following morning.

Follow-up

Patients are seen in a paediatric fracture clinic 1 and 2 wk after manipulation when further radiographs are performed. If alignment is maintained the child is reviewed 3-6 wk later for removal of cast and repeat radiographs. A comprehensive examination is performed at this stage particularly looking for any obvious deformity, range of motion and for clinical evidence of fracture union. If union is felt to be insufficient a cast may be re-applied or splint provided. The child is reviewed 4-6 wk later for a final check. At the point of cast removal advice is given to avoid contact sport for a period deemed appropriate to allow for the bone to strengthen in accordance to Wolff's law[26].

Statistical analysis

All patient data was anonymised. All hospital medical record numbers were retained in the paediatric ED database. Patient demographics, site and nature of injury, time of procedure, sedation or reduction outcomes were documented. Consent forms were kept in the patient files. Pre and post reduction radiographs were taken from our departmental picture archiving and communication systems (PACS). Absolute angulation measurements were taken from the lateral radiographs using angle measuring tool (SECTRA) and measured by AW and PP. A repeated measure *t*-test was utilised to detect if a difference was made. A significance level was set to $\alpha = 0.005$ due to small numbers. The results were then compared to the best available evidence regarding acceptable reduction parameters for different fracture levels of the forearm[7]. Parental satisfaction was assessed using a validated satisfaction score[27].

RESULTS

Demographics

A total of 10 closed unilateral forearm fractures were included in the 4 mo time period. All ten were due to indirect trauma, the majority being due to a fall on an outstretched hand. There were 8 boys and 2 girls. The mean age was 8 years (range 2.2-14.5). There were 6 fractures on the left side and 4 fractures on the right side. There were no cases of compartment syndrome or neurovascular compromise. All children had successful procedural sedation. Two children required topping up to 1.5 mg/kg to achieve appropriate analgesia and sedation. There were no serious adverse events. Vomiting was the most common adverse event, seen in 3 children. All were treated definitively at time of injury and required no further manipulation. No patients were lost to follow-up and all patients reported excellent functional outcomes at discharge as guided by Price *et al*[28]. Figures 2-4 (A-D) demonstrate the variety of fracture types and fracture reduction result.

Radiographic results

There were three Salter Harris Ⅱ fractures of the distal radius, four fractures of the distal third of the radius and/or ulna, two fractures of the mid-shaft of the radius and/or ulna and one fracture of proximal third of the radius. The mean dorsal angulation prior to reduction was 45 degrees (range 17-80). The mean angulation after reduction was 6 degrees (0-15) an improvement that reached statistical significance ($P < 0.001$). Following reduction all fractures were within the parameters recommended by Noonan and Price as acceptable[7]. One patient had an over correction going from a 45 degrees dorsal angulation to 15 degrees of volar angulation, however there was no functional deficit at discharge.

Length of stay

The mean time from fracture diagnosis to sedation administration was 181 min (range 129-234). The mean time to completion of cast application was 20 min (range 7-35). The mean time from sedation to full recovery was 74 min (range 45-120). The mean interval between pre-reduction and post-reduction radiographs was 198 min (range 91-370 min). The mean length of stay in the ED department from arrival to discharge was 311 min (range 213-446).

Cost analysis of ketamine vs general anaesthesia in theatres

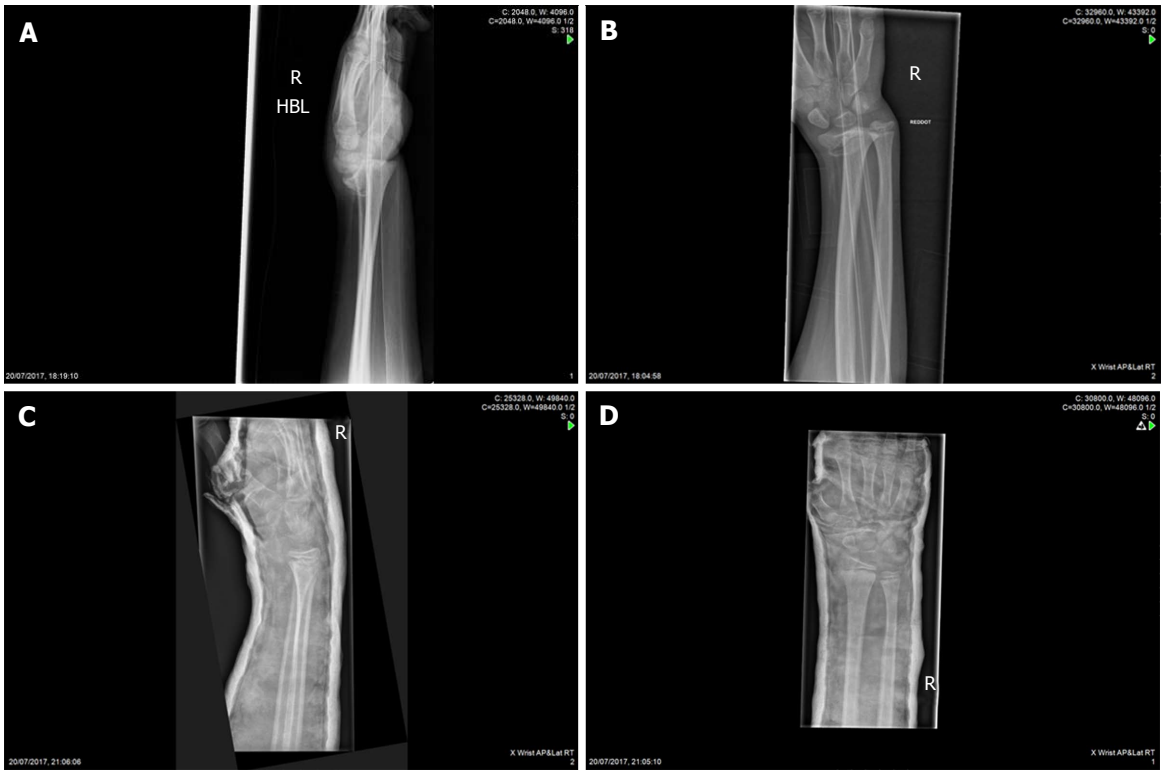
In our trust the health resource group (HRG) code for general anaesthesia in paediatric theatres is £1620 per child. The cost for procedural sedation with ketamine in the paediatric ED was £150 per child. The cost of hospital inpatient admission was not calculated to give a fair comparison. The cost saving is £1470 per child without the addition of cost for admission and loss of earning to the parent/legal guardian if they had to stay with the child. The minimum total financial savings for these 10 children was £14700.

Parental satisfaction questionnaire

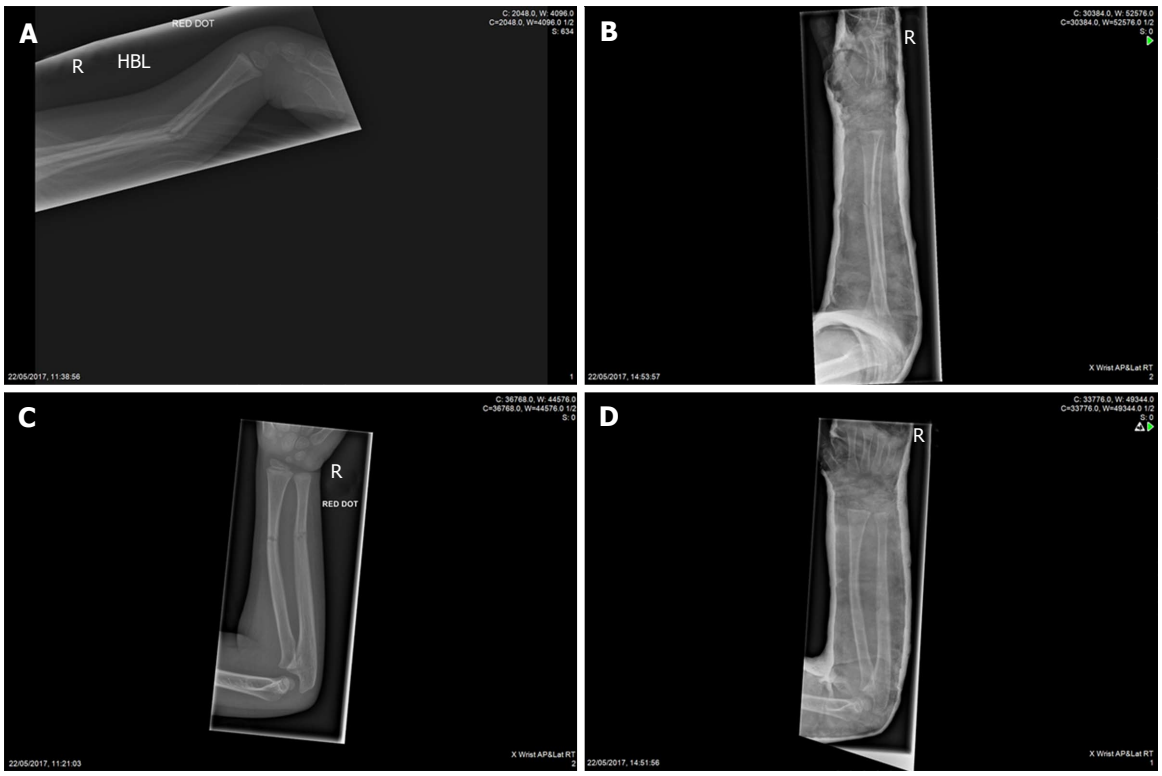
The validated sedation satisfaction score was out of 10, with 0 being not at all and 10 being very satisfied[27]. The mean satisfaction score for all questions was 9.6. The individual scores for each item is seen in Table 1. A score of 10 was the most common result for each questionnaire item.

DISCUSSION

The use of ketamine for procedural sedation in the ED

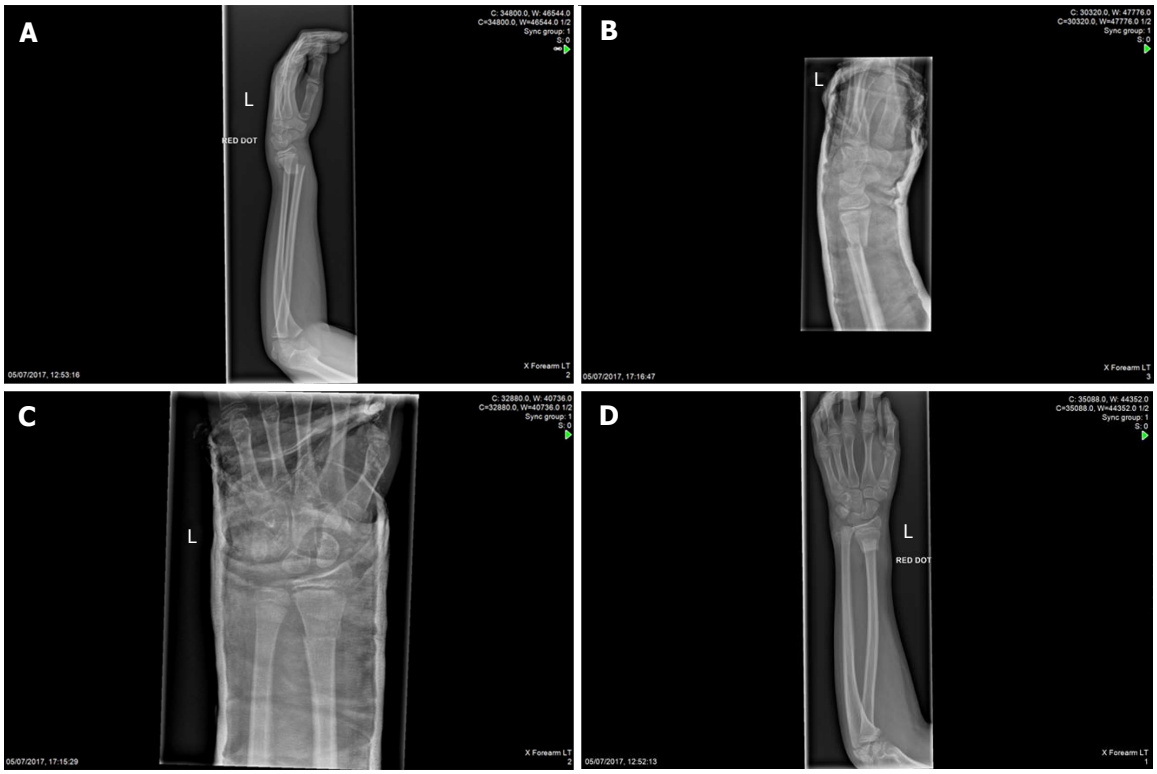


Figures 2 Lateral and anteroposterior radiographs of a Salter Harris II distal radius fracture before (A, B) and after reduction (C, D).



Figures 3 Lateral and anteroposterior radiographs of a midshaft radius and ulna fracture before (A, B) and after reduction (C, D).

in the developed world is gaining popularity[19,24]. In the past few years there is a growing body of evidence supporting its use for successful procedural sedation with a good safety and efficacy profile[29,30]. Serious adverse events are low with the largest prospective cohort study to date reporting a 1.1% risk with no deaths in 6295 children. Vomiting (5.2%) and oxygen desaturation (5.6%) were the most common adverse



Figures 4 Lateral and anteroposterior radiographs of a distal radius and ulna fracture before (A, B) and after reduction (C, D).

Table 1 Parental satisfaction scores

Questionnaire item	Mean	Range	Percent answering "10"
Preparation and instruction given	9.86	9-10	85.7
The care given by nurse pre-procedure	9.43	8-10	71.4
The care given by doctor pre-procedure	9.86	9-10	85.7
The suitability of environment	9.57	8-10	71.4
The experience of the child	8.57	3-10	71.4
The care given by the nurse post-procedure	10	10	100
The care given by doctor post-procedure	9.86	9-10	85.7
Overall parent satisfaction	9.71	9-10	71.4

event found in this multi-centre study[24]. With that risk being further reduced if no other sedatives, such as propofol or fentanyl, were used in conjunction. Earlier works by Green *et al*[31], support these findings as they found 3.9% of children having respiratory adverse events and 8.4% having vomiting. Furthermore they found that co-administering drugs (anticholinergics and benzodiazepines), which were to reduce the risk, in fact made them worse[31].

In our small study, we found no serious adverse events but three children had vomiting. High parental satisfaction scores in this pilot study demonstrate its acceptance amongst the families whose children had procedural sedation. All children had definitive reduction and stabilisation which resulted in an excellent functional outcome. This is contrary to a recent study comparing ketamine *vs* propofol for closed reduction of paediatric both bone forearm fractures which found 35% and 48% unacceptable alignment respectively at 4 wk[32]. However their institution used a splint unlike ours which used a completed moulded cast to maintain reduction. An explanation which they admittedly acknowledge[32]. This finding is supported by another recent study that found only 8.8% children had displaced to an unacceptable standard if a moulded cast was used[13]. An outcome which is impressive considering only Entonox and intranasal diamorphine was used for reduction analgesia[13]. Nevertheless our result reinforces the finding that ketamine can give effective pain relief and sedation to allow thorough manipulation that resulted in fractures that were reduced and immobilised appropriately. The only major disadvantage we found with ketamine in our paediatric ED was the length of stay which was longer than normal. It was 5 h and 11 min which is beyond our National Health Service 4-h target. A target which was met using Entonox and intranasal diamorphine with a mean time of 3 h and 51 min[13]. Still it is a parameter which can be improved as the greatest cause of lost

time is administrative. Our mean result of 181 min to sedation from diagnosis of fracture could improve once this protocol becomes established as routine.

Like many studies, this study has limitations. Due to the range of forearm fracture types along with small numbers, we are unable to give clear fracture displacement cut-off guidelines to which should be safely managed in the ED. However a recent international multi-centre study survey sought to evaluate and establish the clinical practice of reducing paediatric forearm fractures[11]. The results of 111 paediatric ED physicians at 12 tertiary children hospitals found that ketamine was the most commonly (88%) and most frequently (55%) used procedural sedation agent followed by intranasal fentanyl and Entonox. The survey found that most ED physicians would tolerate a "no reduction required policy" for distal forearm fractures up to 20 degrees and 10 degrees for children less than 5 and 10 years old, respectively. It also indicated that majority of ED physicians would prefer fractures with obvious clinical deformity to be managed by the orthopaedic team in theatre due to lack of experience. The survey study also did not define a cut-off which was deemed unacceptable to be treated in the ED. However closely interpreting their survey results, the authors inferred from a clinical vignette with a 25 degree angulated fracture that 74% of physicians would treat that injury in the ED with procedural sedation. In our study we successfully treated fractures with a mean angulation of 45°. Another larger (100 children) study definitively treated 90% of forearm fractures with a mean of 28° of dorsal angulation in the ED with Entonox and intranasal diamorphine[13]. Our and the latter study, both utilised an interdepartmental protocol by which the ED physician gave the sedation and an orthopaedic doctor with fracture reduction experience managed the forearm. This may account for the success in both practical studies and the hesitancy found in the survey study of ED physicians to manipulate deformed fractures. Nonetheless the authors of this paper feel that most paediatric forearm fractures, irrespective of deformity angulation, can be treated in the ED as long as they feel that the fracture pattern is reducible and can be maintained for the duration of its healing.

Other weaknesses acknowledged include, the small number of patients and a lack of comparative procedural sedation agents, but as it was an audit of quality of improvement, the study had to be completed in a reasonable time for a single agent. However our prospective study design meant that we had good data uptake, capturing a variety of outcomes which validates its use in clinical practice. It also ensured a clear protocol, which meant that all children got the same method and delivery of care which makes analysis more robust in terms of reproducibility in everyday practice. Lastly our study demonstrated the success that can be achieved with a team effort using a variety of specialties and skillsets to deliver a service which at heart is at the benefit of the child and the family.

In conclusion, ketamine sedation for children is safe and cost-effective for treating displaced fractures of the radius and ulna, it is associated with a high level of satisfaction.

ARTICLE HIGHLIGHTS

Research background

Children forearm fractures account for up to 40% of fractures that present to the emergency department (ED), majority which could be managed there.

Research motivation

This study improved the quality of care given to children with deformed forearm fractures in the ED.

Research objectives

The main aim of this quality improvement project was to determine if ketamine sedation is a safe and cost-effective way of treating deformed paediatric forearm fractures in the ED.

Research methods

Over a set 4 mo period we prospectively evaluated a new ketamine protocol for paediatric ED procedural sedation. All eligible children with significantly displaced or unstable fractures of the radius and ulna that presented during daylight weekday hours that needed closed reduction and moulded casting were included.

Research results

A total of 10 forearm fractures with a mean 45° angulation deformity were definitively treated in the ED with ketamine procedural sedation. The cost saving was £1470 for each child compared if the patient was taken to theatre. Overall mean parental satisfaction was 9.6 out of 10.

Research conclusions

Ketamine procedural sedation in the paediatric population is a safe and cost effective method for the treatment of displaced forearm fractures.

Research perspectives

Majority of paediatric forearm fracture, irrespective of displacement, can be treated in the ED as long as the fracture pattern is reducible and can be maintained safely in a moulded cast for the duration of its healing.

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RETRACTION NOTE

Retraction note to four articles published in *World Journal of Orthopaedics*

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RETRACTION NOTE

Retraction Note to four articles published in *World Journal of Orthopaedics*: (1) Iwamoto J, Sato Y, Takeda T, Matsumoto H. Return to sports activity by athletes after treatment of spondylolysis. *World J Orthop* 2010; 1(1):26-30 PMID: 22474624 DOI: 10.5312/wjo.v1.i1.26; (2) Iwamoto J, Sato Y, Takeda T, Matsumoto H. Effectiveness of exercise for osteoarthritis of the knee: A review of the literature. *World J Orthop* 2011; 2(5):37-42 PMID: 22474634 DOI: 10.5312/wjo.v2.i5.37; (3) Iwamoto J, Sato Y, Takeda T, Matsumoto H. Analysis of stress fractures in athletes based on our clinical experience. *World J Orthop* 2011; 2(1):7-12 PMID: 22474626 DOI: 10.5312/wjo.v2.i1.7; and (4) Iwamoto J, Takada T, Sato Y, Matsumoto H. Effect of risedronate on speed of sound in postmenopausal women with osteoporosis. *World J Orthop* 2013; 4(4): 316-322 PMID: 24147269 DOI: 10.5312/wjo.v4.i4.316.

These articles[1-4] have been retracted at the request of the Editors-in-Chief as misconduct over authorship of the paper was detected and confirmed.

The Editors-in-Chief recently received communications concerning about the misconduct over the authorship and the integrity of the study. Editorial Office has conducted an investigation and has contacted the authors concerning the allegation. Evidence obtained by the Editorial Office including authors' statements confirmed the misconduct by the authors. One of the conditions of submission of a paper for publication in the journal is that authors declare that all authors must meet authorship criteria. As such these articles represent an abuse of the scientific publishing system. The Editors-in-Chief take a very strong view on this matter and apologies are offered to readers of the journal that this was not detected during the submission process.

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