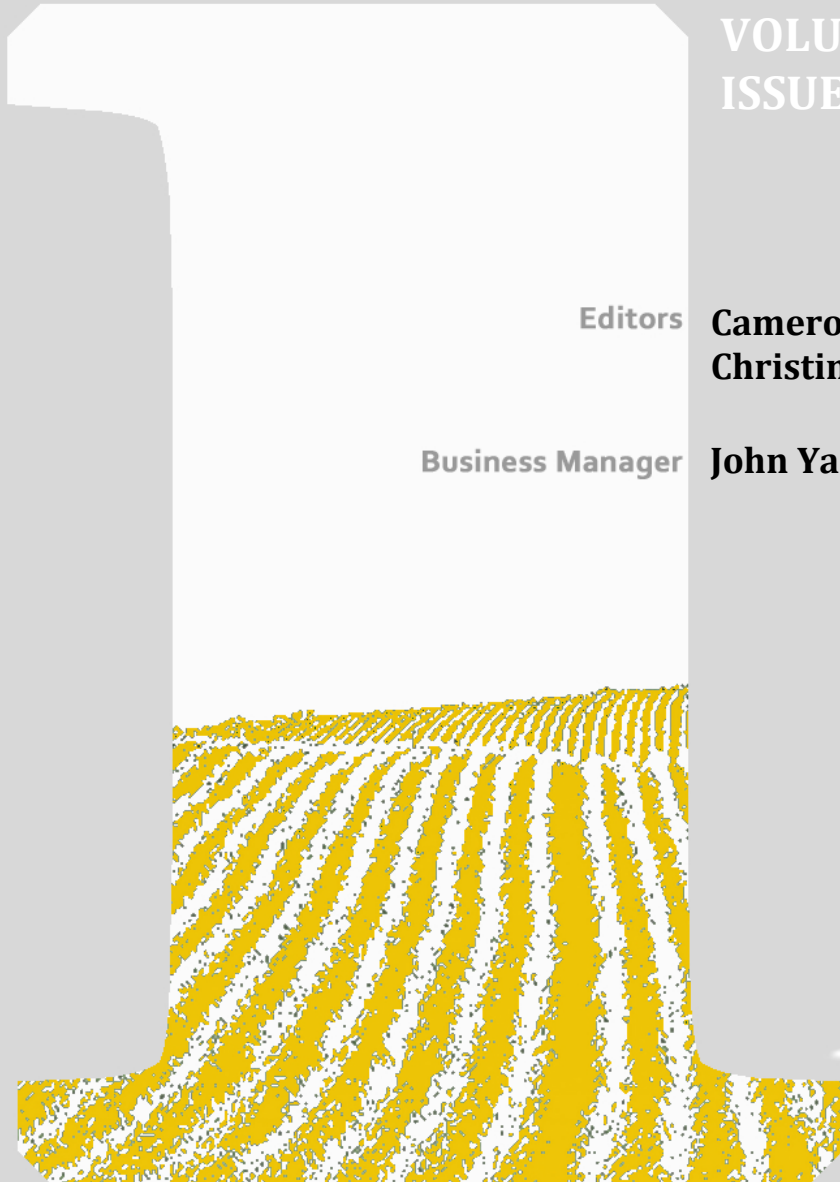




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## Public Notice of Corrections

1. Dale KM, Livermore A, Hanna R, Laham S, Noonan KJ, Halanski M, Lang PJ. Is There a Connection Between Attention Deficit Hyperactivity Disorder and Osteochondritis Dissecans? Iowa Orthop J. 2020;40(1):105-109. PMID: 32742216; PMCID: PMC7368509.

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2. Compton J, Clinger J, Lawler E, Otero J, O'Shaughnessy P. Masks for the Reduction of Methyl Methacrylate Vapor Inhalation. Iowa Orthop J. 2020;40(1):191-193. PMID: 32754006; PMCID: PMC7368533.

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# PONSETI METHOD AFTER WALKING AGE – A MULTI-CENTRIC STUDY OF 429 FEET: RESULTS, POSSIBLE TREATMENT MODIFICATIONS AND OUTCOMES ACCORDING TO AGE GROUPS

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## ABSTRACT

**Objective:** Ponseti method is suitable to treat neglected clubfoot after the walking age. However, limited evidence exists on its effectiveness, outcomes and rate of relapse. **Methods:** 429 clubfeet in 303 patients with no previous treatment and older than one-year were treated with the Ponseti method in 15 centers from seven countries. The median age at treatment onset was three years, and the median follow-up of 1.3 years. Standard Ponseti Method was applied. Bilateral abduction brace was recommended after casting. Patients

were classified according to group ages (<2 years, 2-4 years, >4-8years, >8 years). Feet were evaluated by Pirani score and a clinical outcome classification. Relapses were described in a subset of 103 clubfeet with minimal follow-up of two years.

**Results:** Ponseti method was able to correct the deformity in 87% (373 of 429) of neglected clubfeet, after a mean of 6.8 casts. Residual equinus was treated with percutaneous sectioning of the Achilles tendon in 356 (83%) of 429 clubfeet. A bilateral foot abduction brace was prescribed and used in 70% of children. Relapses occurred in 31% (32 of 103) of clubfeet and were associated with age less than 4 years at treatment onset, and bracing noncompliance.

**Conclusion:** The Ponseti method is effective to correct neglected clubfeet. Relapses occurred in one-third of clubfeet, mainly in children younger than four years and in noncompliance with the brace. Our study reinforces the recommendation for the Ponseti method with no major modification to treat neglected clubfoot in patients after walking age.

**Level of Evidence:** IV

**Keywords:** clubfoot, ponseti method, casts, surgical, neglected clubfeet

## INTRODUCTION

The Ponseti method is the method of choice for the treatment of congenital clubfoot, with well-established effectiveness and reliability in young patients.<sup>1-4</sup> Nevertheless, the management of neglected clubfeet in older patients remains challenging and controversial.<sup>5,6</sup>

Soft-tissue releases,<sup>7-10</sup> fasciocutaneous flaps,<sup>11</sup> osteotomies,<sup>12,13</sup> external fixation distraction,<sup>14-18</sup> arthrodesis,<sup>19-21</sup> talectomy,<sup>22,23</sup> and tarsectomy<sup>23</sup> have been described for the treatment of patients with neglected clubfoot.<sup>24</sup> However, the Ponseti method has the potential for satisfactory correction of recurrent clubfeet after posteromedial

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release,<sup>25-27</sup> neurogenic or arthrogryptic clubfoot,<sup>28,29</sup> and relapses.<sup>30</sup> Therefore, the Ponseti method is likely effective to treat neglected congenital clubfoot in children after the walking age, but all previous studies modified the Ponseti method in minor or major aspects, like the brace protocol and its type, using general anesthesia for tenotomy, advocating short casts in some cases and doing the open lengthening of the Achilles tendon instead of tenotomy.<sup>5,6,30-37</sup> Also, it is not established the brace protocol in older children, and if the results and relapses may change according to specific age groups during childhood or adolescence. We do not know the age limit for applying the Ponseti method, but Haje reported a successful treatment of a 12.9 years old preadolescence<sup>33</sup> and Adegbehingbe et al. treated cases until 16 years old.<sup>36</sup>

We aimed to investigate whether the Ponseti method was able to correct the deformity of congenital clubfoot and eventual subsequent relapses in children after the walking age. Further, we investigated whether modifications in the original Ponseti method are required for the treatment, including the open lengthening of the Achilles tendon, prophylactic transfer of the anterior tibial tendon, or changes in the standard bracing protocol. Finally, we asked whether older age at treatment onset would impact outcomes or increase the rate of relapses following the Ponseti method and we reported a series of cases older than 9 years old, including skeletally mature patients.

## METHODS

This is a retrospective study approved by our Institutional Review Boards. Twenty-three centers were invited to participate in the study; 15 centers from seven countries accepted and responded to standardized questionnaires. Patients with teratogenic clubfoot (i.e., myelomeningocele and arthrogryposis), who underwent previous surgery, and who had not started walking were not enrolled. We evaluated 303 patients older than one year with neglected clubfoot who were treated between 2004 and January 2017.

The foot manipulation and casting were performed as described by Ponseti.<sup>38-40</sup> In each of the 15 centers, one trained pediatric orthopaedic surgeon with experience in the Ponseti method conducted the treatment. During the manipulation and casting, we aimed for enough foot abduction able to provide complete resolution of the cavus and varus deformities before the surgical correction of the equinus deformity. Achilles tendon lengthening was performed by complete percutaneous sectioning.<sup>40</sup> Following the surgery, a long leg cast with maximal ankle dorsiflexion and foot abduction was used during three to six weeks. To prevent relapses, we recommended a protocol with standard bilateral foot abduction brace 23 hours per day. After this period, bracing was recommended 14 hours

**Table 1. General Outcome Classification for Patients with Neglected Clubfoot Treated with the Ponseti Method**

<b>Excellent</b>	foot fully plantigrade with at least than 10 degrees of ankle dorsiflexion; absence of residual deformities or pain
<b>Good</b>	foot fully plantigrade with zero to 10 degrees of ankle dorsiflexion; absence of residual deformities or pain
<b>Regular</b>	no pain, little residual deformity, requirement for localized surgical treatment beyond the Achilles tendon lengthening and tibial anterior transfer
<b>Poor</b>	failure of initial correction and need for extensive soft tissue release (posteromedial release)

Source: Nogueira et al., 2017.

per day, or at least night-time use until the age four years. Patients older than three years had the recommendation to use the brace 14 hours per day or at least night-time use for at least one year. The authors were asked to report for variations in the protocol that occurred in response to the lack of compliance with the abduction brace, child's age and activities.

The standardized questionnaire included the following patient's data: age; sex; family history; treatment in public or private institution; the Pirani scores<sup>41</sup> before and after casting; number of casts needed for deformity correction prior to the residual equinus treatment; type of surgery to correct the residual equinus; decision for prophylactic transfer of anterior tibial tendon; anesthesia protocol; compliance with the bracing protocol; presence or not of relapse; modality of treatment following a relapse (casting, transfer of anterior tibial tendon; repeated Achilles percutaneous tenotomy or z-lengthening; soft-tissue releases and osteotomies); duration of follow-up; presence of complications related to the treatment, and the overall outcome classification<sup>42</sup> (Table 1). Failure was defined by poor and regular outcomes according to clinical outcomes classification at final follow-up: posteromedial release (considered poor result) or posterior release and any other additional surgery, but anterior tibial tendon transfer (considered regular result). Data related to the compliance with the brace protocol was available for 401 (93%) clubfeet.

## Statistical analysis

Demographic data were described using frequency, mean and standard deviation ( $\pm$ SD), or median and interquartile range (IQR, percentiles 25th to 75th). Patients were categorized in groups by age at the initial treatment: group 1 younger than 2 years, from 2 to 3 years, older than 4 years up to 8 years, older than 9 years of age. To compare variables before and after treatment and between age groups, we used the mixed effects generalized model



**Table 2. Demographic Characteristics of the Cohort**

Characteristic of the cohort (303 patients)		
Age at treatment onset (years)	3.0	(1.6 to 5.0)
Sex (% male)	204	(67%)
Family history of clubfoot	36	(11%)
Follow-up (years)	1.3	(0.7 to 2.5)
Affected side		
Bilateral	126	(42%)
Right (unilateral)	94	(31%)
Left (unilateral)	83	(27%)
<b>Subset of patients with follow-up greater than 2 years (71 patients)</b>		
Follow-up (years)	3.4	(2.5 to 4.5)

Values are expressed by median and interquartile range (25th to 75th percentiles), or number of patients and percentage.

of linear regression, with random and fixed effects. A multilevel modeling approach was used to control for the lack of independency in bilateral clubfeet in the same patient. Values of  $p < 0.05$  were considered significant.

### RESULTS

The median age at treatment onset was 3.0 years (interquartile range [IQR], 1.6 to 5.0 years) and the median follow-up was 1.3 years (IQR, 0.7 to 2.5 years). Nine patients were aged over 15 years in this series, and the oldest patient was 30 years old at treatment onset. Of 303 patients, 204 patients were male (67%); 36 (11%) had a family history of clubfoot, and 126 (42%) presented with bilateral clubfeet, leading to a total of 429 clubfeet. Treatment was conducted in public institutions in 91% (277 of 303) of cases. A subset of 71 (23%) of the 303 patients (103 [24%] out of 429 feet) was followed for more than two years (median follow-up, 3.4 years; IQR, 2.5 to 4.5 years) (Table 2).

We found that the Ponseti method was able to correct the deformity of congenital clubfoot, with a proportion of good and excellent overall outcomes of 87% (Table 3, Figures 1-4). The method failed to correct the deformity in 54 (13%) of 429 clubfeet (regular and poor outcomes), and an extensive posteromedial release was performed only in 23 clubfeet (5%). The clubfeet required an average ( $\pm$ sd) of  $6.8 \pm 3.3$  casts for correction, and 394 (92%) out of 429 feet required surgery for residual equinus. Complications included skin lesions (3%; 13 out of the 429 feet), infection (one foot) and rocker-bottom deformity (one foot). The mean Pirani score was  $5.0 \pm 1.1$  at the initial presentation, and  $0.5 \pm 0.9$  after treatment ( $p < 0.001$ ).

**Table 3. Outcomes of the Ponseti Method for Neglected Clubfoot Treatment According to Modality of Achilles Tendon Lengthening**

	Total n=394 clubfeet underwent surgical lengthening of the Achilles tendon	Percutaneous tenotomy (356 feet)	Open lengthening (38 feet)	P-value
Age at treatment onset (years)	2.8 (1.6 to 4.6)	5.1 (2.0 to 13.2)	<0.001	
Number of casts (mean $\pm$ sd)	$6.8 \pm 2.8$	$8.6 \pm 6.2$	0.002	
General outcomes				0.39
Excellent	175 (49%)	17 (44%)		
Good	134 (38%)	15 (39%)		
Regular	28 (8%)	2 (5%)		
Poor	19 (5%)	4 (10%)		
Pirani classification				
Initial (mean $\pm$ sd)	$5.1 \pm 1.1$	$5.1 \pm 1.2$	0.93	
Final (mean $\pm$ sd)	$0.5 \pm 0.9$	$0.7 \pm 1.0$	0.31	

Values refer to the median and interquartile range (25th to 75th percentiles), frequency and percentage, or mean  $\pm$  standard deviation (sd).

No major variations in the standard protocol were identified. The percutaneous sectioning of the Achilles tendon was performed in 356 feet (83%) and the open z-lengthening in 38 (9%) of 429 clubfeet as the index correction of equinus deformity. Percutaneous sectioning was performed under local anesthesia in 247 (69%) of the 356 procedures. Both surgical modalities of residual equinus correction had similar proportion of good or excellent overall outcomes ( $p=0.39$ ; Table 3) and final Pirani scores (mean,  $0.5 \pm 0.9$  compared with  $0.7 \pm 1.0$ ;  $p=0.31$ ). However, the percutaneous sectioning was performed at younger ages (median, 2.8 years [IQR 1.6 to 4.6 years] compared with 5.1 years [IQR 2.0 to 13.2 years;  $p < 0.001$ ], and in clubfeet that required a lower number of casts (mean,  $6.8 \pm 2.8$  compared with  $8.6 \pm 6.2$ ;  $p=0.002$ ). In 22 feet (5%) out the 429 clubfeet, the anterior tibial tendon was prophylactically transferred to the third cuneiform, along with the surgical equinus correction. A bilateral foot abduction brace was used in 82% (329 of 401) of clubfeet, but we observed inadequate use in 49 (12%) feet. Because of unavailability of bilateral foot abduction brace, bracing had never been initiated in 63 (16%) of 401, and a unilateral ankle-foot orthosis was prescribed for nine feet (2%), yielding a total rate of noncompliance with the abduction brace of 30% (121 of 401) (Table 4).

Treatment starting between four and eight years was associated with lower proportion of good and excellent outcomes compared with the other age groups



Figure 1. 16 years and 4 months old boy with left non-treated clubfoot from Brazil. A. Pre-treatment. B. First cast. C. After 6 casts and tendoAchillis lengthening. D. 4 years follow-up.



Figure 2. 6-year-old boy with right clubfoot from Brazil. A. Pre-treatment. B. 2 years follow-up - after 6 casts and tenotomy under local anesthesia. C. 8 years follow-up.





Figure 3. Two 5-year-old boys with bilateral clubfoot from Egypt. A. Pre-treatment. B. After treatment with 5 casts and tenotomy.



Figure 4. 30-year-old woman with right clubfoot from Equador. A. Pre-treatment. B. After treatment. 22 months follow-up.

**Table 4. Outcomes of the Ponseti Method for Neglected Clubfoot Treatment**

Values refer to the frequency and percentage or mean ± standard deviation (sd).	
Outcomes (n=429 foot)	p-value
Number of casts (mean ± sd)	6.8 ± 3.3
Achilles tendon surgery	
None	35 (8%)
Percutaneous tenotomy	356 (83%)
Open z-lengthening	38(9%)
Prophylactic transfer of the anterior tibial tendon (% yes)	22 (5%)
Bracing *	
Bilateral foot abduction brace (adequate use)	280 (70%)
Bilateral foot abduction brace (inadequate use)	49 (12%)
Unilateral ankle-foot orthosis	9 (2%)
None	63 (16%)
Noncompliance with the bracing protocol *	121 (30%)
Pirani classification	p<0.001
Initial (mean ± sd)	5.0 ± 1.1
Final (mean ± sd)	0.5 ± 0.9
General outcomes	
Excellent	211 (49%)
Good	164 (38%)
Regular	31(7%)
Poor	23(5%)

\*Values available for 401 (93%) of 429 clubfeet

(76% compared with values  $\geq 87\%$ ;  $p=0.002$ ) (Table 5). We also observed that the proportion of noncompliance with the abduction brace was greater between four and eight years (43% compared with less than 32%;  $p<0.001$ ). The open z-lengthening of the Achilles tendon was performed with a greater proportion in patients with or older than nine years (30% compared with less than 9%;  $p<0.001$ ). However, no difference was observed in the number of casts (6.8 to 7.1;  $p=0.80$ ), and final Pirani score (0.4 to 0.6;  $p=0.20$ ) between age groups.

Within the subset of 103 clubfeet with minimum follow-up of two years, relapses were observed in 32 clubfeet (31%). A higher proportion of relapses was observed when the treatment started before the age four years (38% in age 1 to 3 years compared with 12% in age  $\geq 4$  years;  $p=0.01$ ) (Table 5). Noncompliance with the

bracing protocol was also associated with an increased proportion of relapses (48% compared with 25% for the adequate brace use;  $p=0.04$ ). All nine clubfeet treated with unilateral ankle-foot orthosis relapsed. No relapses were observed in six clubfeet submitted to prophylactic transfer of the anterior tibial tendon. Serial casting was indicated to treat recurrence in 23 of 32 relapsed clubfeet (72%), with associated anterior tibial tendon transfer in 14, and repeated Achilles tenotomy in six clubfeet. Six feet (19%) underwent anterior tibial tendon transfer (3) or Achilles tenotomy (3) without prior casting, and the remaining three feet (9%) were not treated.

## DISCUSSION

Neglected clubfoot is a major disabling condition whose treatment has been considered to be largely surgical, involving time-consuming, complex procedures with challenging anesthetic monitoring.<sup>43</sup> Their results are associated with rigid painful feet in long-term.<sup>44,45</sup> More recently, the upper limit of age to perform the Ponseti method has been extended to older children,<sup>5,6,30-37</sup> and our study showed successful treatments in adolescents and adults. Despite initial encouraging outcomes, there is limited evidence about the potential of the Ponseti method to correct neglected clubfoot deformities. One of the strengths of the current study is that is the largest series of the Ponseti method for treatment of neglected clubfeet in older children, including the oldest case reported up to now. We found that the method is able to correct the deformity in the majority of patients with a low rate of failures and complications. No major modifications in the original technique were required. Furthermore, we observed relapses in one-third of clubfeet that could also be treated using the Ponseti method principles.

Following the results of publications from the last decade,<sup>5,6,30-37</sup> our study confirmed that the Ponseti method has the potential to correct the primary clubfoot deformity in ambulatory patients. We identified good and excellent results in 87% of feet. To our knowledge, Lourenço and Morcuende<sup>5</sup> firstly reported in 2007 the use of the Ponseti method in 24 neglected clubfeet, with 66% of good results. In their study, the correction required nine casts and percutaneous Achilles sectioning in all clubfeet. Subsequent studies<sup>31-36</sup> also reported favorable outcomes in neglected clubfeet correction using the Ponseti method. The mean number of casts varied from six to 12, and 50% to 100% of clubfeet required surgery for residual equinus, including percutaneous sectioning or open z-lengthening of the Achilles tendon with or without posterior release.<sup>31-36</sup> In our study, we observed a mean of 6.8 casts for the initial deformity correction, which is in line with these results.<sup>36</sup> However, we observed that 92% of clubfeet required percutaneous Achilles tenotomy



**Table 5. Outcomes of the Ponseti Method for Neglected Clubfoot Treatment According to Age Groups**

<b>Total n=429 clubfeet</b>	<b>1 year</b>	<b>2-3 years</b>	<b>4-8 years</b>	<b>&gt; 9 years</b>	<b>p-value</b>
Number of clubfeet	143	129	110	47	
Number of casts (mean ± sd)	6.8 ± 4.3	6.7 ± 2.7	6.6 ± 2.5	7.1 ± 2.8	0.80
Achilles tendon surgery					<0.001
None (35 feet)	14 (10%)	10 (8%)	10 (9%)	1 (2%)	
Percutaneous tenotomy (356 feet)	121 (85%)	113 (88%)	90 (82%)	32 (68%)	
Open lengthening (38 feet)	8 (6%)	6 (5%)	10 (9%)	14 (30%)	
Brace noncompliance*	27 (20%)	27 (22%)	43 (43%)	15 (32%)	<0.001
General outcomes					0.002
Excellent	85 (59%)	65 (50%)	38 (34%)	23 (49%)	
Good	49 (34%)	51 (40%)	46 (42%)	18 (38%)	
Regular	3 (2%)	8 (6%)	16 (15%)	4 (9%)	
Poor	6 (4%)	5 (4%)	10 (9%)	2 (4%)	
Pirani classification					
Initial (mean ± sd)	5.0 ± 1.1	5.2 ± 1.1	4.9 ± 1.3	4.8 ± 1.3	0.20
Final (mean ± sd)	0.5 ± 1.0	0.4 ± 0.7	0.6 ± 1.0	0.4 ± 0.5	0.20
<b>Follow-up &gt; 2 years (n=103 clubfeet)</b>	<b>1 years</b>	<b>2-3 years</b>	<b>4-8 years</b>	<b>≥ 9 years</b>	<b>p-value</b>
Age (mean ± sd / range minimum - maximum)	1.4 ± 0.3 (1.0 - 1.9)	2.5 ± 0.6 (2.1 - 3.9)	6.2 ± 1.5 (4.1 - 7.9)	11.8 ± 1.8 (10.1 - 15.6)	<0.001
Number of clubfeet	43	34	18	8	
Brace noncompliance <sup>Δ</sup>	7 (19%)	7 (22%)	6 (33%)	1 (12.5%)	0.59
Duration of follow-up	3.5 ± 1.4	3.5 ± 1.2	5.9 ± 3.9†	5.3 ± 3.0	0.002
General outcomes					0.53
Excellent	25 (58%)	15 (44%)	11 (61%)	7 (87%)	
Good	17 (39%)	17 (50%)	4 (22%)	0	
Regular	0	0	1 (66%)	0	
Poor	1 (2%)	2 (6%)	2 (11%)	1 (13%)	
Pirani classification					
Initial (mean ± sd)	4.7 ± 1.2	5.1 ± 0.8	4.9 ± 1.4	5.3 ± 0.6	0.28
Final (mean ± sd)	0.4 ± 0.6	0.4 ± 0.5	0.3 ± 0.4	0.3 ± 0.4	0.63
Relapses (total 32 clubfeet)	16 (37%)	13 (38%)	2 (11%)	1 (13%)	0.01

Values refer to the frequency and percentage or mean ± standard deviation (sd).

\* Values available for 401 clubfeet (131 group 1 year; 125 group 2-3 years; 99 group 4-8 years; 46 group > 9 years)

<sup>Δ</sup>Values available for 94 clubfeet (36 group 1 year; 32 group 2-3 years; 18 group 4-8 years; 8 group > 9 years)

† The group between 4 and 8 years is significantly older than the other age groups. No significant differences were found between groups 1 year, 2-3 years and ≥9 years

or open z-lengthening to correct the residual equinus, while Adegbehingbe et al.<sup>36</sup> reported a proportion of 51%. Interestingly, we observed no differences in the number of casts, final Pirani score and overall outcomes between the younger and older age groups. Nevertheless, a greater proportion of failures was observed when the treatment started between four and eight years, and one possible explanation is the greater proportion of bracing non-compliance.<sup>46</sup> Yagmurlu et al. reported that the effectivity of Ponseti method may decrease with age in patients with neglected clubfoot aged from one to 6 years.<sup>36</sup> Also Sinha et al. reported an increasing number of casts required for maximal correction with increasing age, treating 30 patients between one to 10 years.<sup>36</sup>

We observed that no major modifications in the original Ponseti method are required to correct the primary deformity in neglected clubfoot. Clubfeet were manipulated and long-leg casts were changed mostly every week, similarly to several other studies.<sup>6,31-33,35,36</sup> However Lourenço and Morcuende<sup>5</sup> used long-leg casts changed every two weeks, defending that could possibly allow more time for the remodeling of soft tissue and osteocartilaginous structures. Longer casting period could cause osteoporosis and may not be recommended. In our study, the percutaneous sectioning of the Achilles tendon was performed in 83% of clubfeet without reports of complications or calcaneal gait. Most studies reported no major complication following the percutaneous sectioning of the Achilles tendon in children after the walking age, performed in 45% to 100% of neglected clubfeet.<sup>5,6,31,33,35,36</sup> Nevertheless, the upper limit of age has not been established for a complete percutaneous sectioning of the Achilles tendon in clubfoot,<sup>37,47,48</sup> and further studies will be important to assess the quality of the tendon healing in older patients. Nogueira and Amaral<sup>49</sup> reported complete healing after total percutaneous tenotomy after 6 weeks, and there was no reported planovalgus feet in this study, as in the systematic review including 654 feet.<sup>50</sup> Yagmurlu et al.<sup>32</sup> and Bashi et al.<sup>34</sup> performed the open Achilles z-lengthening in 55% and 100% of clubfeet, respectively. In our study, the open z-lengthening was performed only in 9% of feet, and its indication increased for older ages and feet requiring greater number of casts. We also observed that a minority of neglected clubfeet (5%) underwent a prophylactic transfer of the anterior tibial tendon. Although no consistent indication exists concerning the prevention of relapses, the prophylactic transfer may be worthwhile for children older than four years, from distant regions with potential for follow-up loss.

The standard bilateral foot abduction brace was used in 70% of children in our series, and we showed that relapses occurred mostly in cases that did not used braces or had brace non-compliance. We recommend the use of bilateral

foot abduction brace trying to prevent relapses, especially for children younger than four years. Night-time use was recommended in ambulatory patients, 14 hours a day. Our bracing protocol was in accordance with most neglected clubfoot series in literature<sup>6,32,33,35,36,50</sup> suggesting that the use of bilateral foot abduction brace, as described by Ponseti,<sup>39</sup> is possible even for ambulatory patients. In contrast, Lourenço and Morcuende<sup>5</sup> and Bashi et al.<sup>34</sup> reported the use of unilateral ankle-foot orthosis. While Lourenço and Morcuende<sup>5</sup> and Bashi et al.<sup>34</sup> reported good results using unilateral foot-ankle orthosis, its use in our study was associated with relapses in all clubfeet. Some studies do not even report the use of braces for some or all patients<sup>5</sup> and others did not document the percentage of patients that worn the splint as well as the rates of recurrence.<sup>5</sup>

Relapses have been reported from 0 to 33% of neglected clubfeet treated with the Ponseti method.<sup>31</sup> Our proportion of relapses of 31% was according to the literature, however we evaluated relapses only in clubfeet with at least two years of follow-up. Sinha et al. had 23% of recurrence in a minimum follow up of 2 years and the common feature in all relapsed cases was non-adherence to bracing protocol.<sup>35</sup> Intermediate and long-term studies will be worthwhile to understand all the factors associated with relapse in neglected clubfoot. Possibly, the potential for foot growth in younger patients may be a predisposing factor for relapses. Our results suggest that patients younger than four years at the treatment onset and abduction brace non-compliance are associated with a higher rate of relapses.

We found it difficult to predict a treatment prognosis before its beginning, taking into account factors such as initial clinical aspect or Pirani score. Chu et al. reported that the Catterall/Pirani and Demeglio/Bensahel classifications had low correlation with the number of Ponseti casts needed for the correction of CTEV and suggested that it is necessary to develop new classifications to help predict the time of treatment and the risk of relapse.<sup>51</sup> However, Dyer and Davis reported that the Pirani score has a predictive value, and those with scores higher than four tend to require more than four casts for correction.<sup>52</sup> We believe that this score presents a lower value in neglected cases and has a poor predictive or prognostic value, but it may occasionally be useful during treatment follow-up.

We acknowledge several limitations in our study. First, several patients were lost to follow-up and only one-quarter of clubfeet were followed for a minimum of two years. It is important to report the results of all cases, and not only of the ones that had follow-up, because that helps to understand the treatment's potential for correction of the deformity. The long-term follow-up helps to understand the importance of the brace protocol, relapses and rates of osteoarthritis. The ideal follow-up probably

is to follow the patient until skeletal maturity to assess relapses and until the end of life to assess osteoarthritis. Although x-rays examinations before, during, and after the Ponseti treatment may be done in order to precisely assess articular relationships and joint orientations of the foot and ankle, and could help accessing very long term results, it is difficult doing that in poor developing countries and it is not necessary in low or midterm follow-up because those patients with no pain or no foot deformity usually are satisfied with treatment. Although general outcome classification used did not assess muscle function, it could be done. Concerns about selection and transfer bias may have compromised our analysis. These biases were difficult to overcome because many patients were referred to our clubfoot clinics from distant, poor regions of developing countries, thus explaining at least in part the follow-up loss. Second, the retrospective approach of data collection may have suffered bias according to the subjectivity of the observer to classify the overall outcomes. Third, hypo-correction and brace low quality may also have compromised the bracing compliance. Finally, our study lacks a control group of patients with neglected clubfoot who underwent surgical treatment involving traditional soft tissue release or external fixator distraction. However, Dobbs et al.<sup>45</sup> already reported high rates of osteoarthritis, fusion and pain after posteromedial release and that should not be underemphasized. A well-conducted prospective study design with a large series is warranted to answer some issues raised above, but would have the bias of being done mostly in developing countries where many children do not return enough time for long term follow up.

### CONCLUSION

We conclude that the Ponseti method is an effective and safe treatment to correct the primary deformity in a large series of neglected clubfoot, with more than 85% of good and excellent outcomes, consistent with what was reported in a recent systematic review, with a similar number of patients.<sup>50</sup> No major modification is required to treat congenital clubfoot and further relapses in patients after the walking age. Relapses occurred in almost one-third of clubfeet, mainly in children younger than four years and in those non-compliant with the abduction brace. Most of the relapses were treated with repeated casting, tendon Achilles percutaneous section or lengthening and anterior tibial tendon transfer.

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# BUCKLING DOWN ON TORUS FRACTURES - ASSESSING TREATMENT PREFERENCES AND PERCEIVED MANAGEMENT BARRIERS AT A SINGLE INSTITUTION

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## ABSTRACT

**Background:** Pediatric buckle fractures of the wrist can be safely managed in 'minimalist' fashion with splinting and limited follow-up; however, traditional means of treatment remain prevalent. The purpose of this study was to 1) evaluate preferences for buckle fracture management among providers at a single institution and 2) identify factors influencing clinical decision-making and barriers to implementation of minimalist practices.

**Methods:** A 13 question survey was developed split into three sections: 1) Demographics, 2) Preferred management, and 3) Influential factors. The survey was distributed to 32 providers within our hospital system involved in buckle fracture management via email over a 1 year period. Descriptive statistics of responses were performed to address study aims.

**Results:** The survey participation rate was 72%. Respondents had 12.2+/-12.5 (Range: 1-41) years of experience. Casting of buckle fractures was preferred by 56.5% of providers. Most (77%) were aware of literature supporting minimalist strategies. Family preferences (59.1%) and compliance concerns (54.5%) were cited as the biggest barriers to implementing these practices. Colleague recommendations and patient and caregiver preferences had the strongest influence on providers' practice. Following completion, 88.2% of providers stated they would change or consider changing their practices.

**Discussion:** Despite awareness of the evidence base, a casting preference still exists. While other aspects of the minimalist approach were popular, prior work suggests this does not necessarily

translate into practice. Commonly cited barriers include family preferences and compliance concerns; however, awareness of these issues may enable change.

**Level of Evidence:** III

**Keywords:** buckle fracture, torus fracture, splint, cast, treatment preference survey

## INTRODUCTION

Buckle fractures of the distal forearm in children and young adolescents are common injuries seen by providers caring for pediatric musculoskeletal injuries. Due to their inherent stability, growing evidence has suggested that treatment-related complications are rare regardless of management.<sup>1-8</sup> As such, many providers have adopted a 'minimalist' approach<sup>6</sup> to the management of these injuries using removable immobilization acutely and no radiographic follow-up, which results in improved patient and family satisfaction while reducing unnecessary clinic visits and cost.<sup>1,4,8,9</sup> However, despite the breadth of evidence documenting the safety of this treatment strategy and numerous purported benefits, adoption of this approach has not been widespread. Recent work at our own institution demonstrated less than 10% of patients were managed in this fashion, with persistent utilization of casting and routine clinical and radiographic exams similar to the management of less stable wrist and forearm fractures.<sup>10</sup> And studies across multiple countries and providers types have identified residual preference for casting strategies of management as opposed to this minimalist approach.<sup>11-13</sup> Such observations prompted the examination of factors affecting provider clinical decision-making and potential barriers to implementing minimalist strategies.

Clinicians face numerous barriers to adopting new standards of practice. Potential barriers in the realm of management of buckle fractures include lack of familiarity with the recent literature, prior provider experiences, strong colleague opinions or influence, patient and caregiver preferences, concerns regarding patient compliance with splint wear, or providers' lack of confidence in their ability to accurately identify fractures and patients appropriate for this treatment strategy. In prior surveys performed among emergency medicine (EM)<sup>12</sup> and pediatric orthopaedic<sup>11</sup> providers, Boutis et al. found that concerns regarding patient compliance and safety are the

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biggest perceived barriers to broader implementation of minimalist practices. Preferred management, knowledge of the evolving literature base and factors influencing the management of this injury have not been explored outside of these communities highly experienced in pediatric patient care.

Previous observations at our institution set forth a multi-faceted effort to explore rationale and affect change in the management of pediatric buckle fractures. The primary aims of this study were to 1) evaluate management preferences among a diverse group of providers routinely caring for this injury at a single center and 2) identify factors most influential on clinical decision-making and barriers to changing practice. We hypothesized that provider preferences would differ from previously documented actual practice<sup>10</sup> and that patient and caregiver preferences would be a major influence on decision-making in this realm of pediatric care. Findings from this study will help to characterize factors impacting patient management beyond the evidence base.

## **METHODS**

In order to explore provider rationale for clinical decision-making in the management of pediatric buckle fractures of the distal forearm, a survey of practitioners at our institution commonly managing these injuries was performed. Following precedent set by previously published physician surveys on this topic,<sup>11,12</sup> survey reporting was performed in accordance with the Checklist for Reporting Results of Internet E-Surveys.<sup>14</sup>

### **Survey Design and Content**

The study survey was developed after literature review and investigator brainstorming to formulate questions addressing our study aims. The survey underwent review by three orthopaedic surgeons and two research division personnel for question clarity and appropriateness. The final survey was composed of 13 questions in three sections: 1) Demographics, 2) Preferred Management, and 3) Approach to Decision Making (Barriers and Influential Factors). Completion of certain demographic questions were kept optional to protect provider anonymity given the sample size (see Appendix). The study was approved by our center's Institutional Review Board.

### **Study Population**

The target study population were providers capable of practicing independently (including non-resident/fellow MD/DO, ARNP or PA) at our institution who regularly managed these injuries in the orthopaedic hand and pediatric clinics, the orthopaedic after hours clinic, or the pediatric emergency department. Thirty-five providers were identified matching these characteristics from

multiple training backgrounds including Orthopaedics, Physical Medicine and Rehabilitation, Family Medicine, Pediatric and Emergency Medicine. Three providers (two pediatric orthopaedists and one hand surgeon) involved in survey design were excluded. Thus, 32 providers were ultimately contacted for participation.

### **Survey Administration and Collection**

Survey functionality and usability was assessed via trial completion using the website link and online form prior to distribution. The survey was closed and accessible only to those invited for participation. Questions were non-adaptive and presented in a set order with each survey section on a separate page. Due to inclusion of an evidence-based knowledge question in the 3rd section, providers were unable to review or revise their answers to the Preferred Management section after completion.

The survey was distributed via a single, directed email from the first and senior authors of the study to the 32 providers identified. Emails contained a brief background of the study and a website link to the survey. Distribution was completed between August 2016 and September 2017. Survey responses were collected and managed using REDCap (Research Electronic Data Capture)<sup>15</sup> tools hosted at our institution. No compensation was offered for survey completion.

### **Statistical Analyses**

Statistical analyses were performed using JMP® PRO Version 13.0 [SAS Institute, Cary, NC]. For the purposes of ensuring a cohort of unique providers and to facilitate comparison of demographic information with provider responses, only surveys with 2 or more completed sections were included in our study analyses. Provider demographics were then reviewed prior to analysis to assess for multiple entries from the same individual. No duplicates were identified. A non-response analysis could not be performed due to the methodologic design of the survey and protection of anonymity.

Descriptive statistics were used to summarize responses to demographics, preferred practices, barriers, and factors influential in the decision-making process. Providers were then categorized as 'traditional' or 'minimalist' managers based on their preferred immobilization device (Cast vs. Splint) and their opinion regarding the routine use of radiographs in follow-up (Yes vs. No). Bivariate analyses were performed within each of these categorized cohorts to assess for associations with provider training (Categorical: Orthopaedic Surgery - Yes or No) and years in practice (Continuous). Two tailed student t-tests were performed for continuous variables and Fisher's Exact test was used for categorical variables due to our limited sample size. A p-value <0.05 was considered significant.

**Table 1: Provider Respondent Demographics**

Demographic Variable	Mean +/- SD (Range) or Frequency (%)
Years In Practice (N=23)	12.2 +/- 12.5 (1-41)
Provider Type (N=23)	
MD/DO	16 (69.6%)
PA	6 (26.1%)
ARNP	1 (4.3%)
MD/DO Training Specialty (N=16)	
Orthopaedics	6 (37.5%)
Declined to Reply	3 (18.8%)
Physical Medicine & Rehabilitation	2 (12.5%)
Emergency Medicine	2 (12.5%)
Pediatrics	2 (12.5%)
Family Medicine	1 (6.3%)
Proportion of Practice Treating Pediatric Patients (N=23)	
<25%	6 (26.1%)
25-50%	11 (47.8%)
50-75%	1 (4.3%)
>75%	5 (21.7%)

Demographics of the 23 participating providers

**RESULTS**

**Survey Respondents**

Of the 32 recruited providers, 23 unique providers completed two or more sections (Demographics and Preferred Management) and 20 completed the entire survey. This represents participation and completion rates of 72% and 63%, respectively. The survey was viewed or started 30 times; however, a unique respondent view rate could not be calculated based on the anonymity of survey design. The demographics of included respondents are shown in Table 1.

**Preferred Management of Buckle Fractures**

The majority of providers preferred to manage buckle fractures using cast immobilization (56.5%), follow-up within 2 weeks (52.2%), immobilization for 3-4 weeks (78.3%) and return to full activities after 5-6 weeks (60.9%). Fifty-two percent of providers stated follow-up radiographs were not necessary unless the patient had reinjury, pain at follow-up or other complications. Management preferences of survey respondents are further summarized in Table 2.

**Barriers, Influencers and Willingness to Change**

Providers most frequently cited family preferences (59.1%) and concerns about patient compliance with removeable immobilization devices (54.5%) as barriers to implementing minimalist practices. Respondent

**Table 2. Provider Preferred Management**

Management Question	Response Options	n = 23
How do you prefer to immobilize pediatric buckle fractures of the wrist in the acute setting?	Cast Splint Soft Dressing No Immobilization	13 (56.5%) 10 (43.5%) 0 (0%) 0 (0%)
After initial presentation, when do you advise these patients be seen at first follow-up?	Never unless re-injury, continued pain, or complication occurs 1-2 weeks 3-4 weeks 5-6 weeks >6 weeks	1 (4.3%) 12 (52.2%) 10 (43.5%) 0 (0%) 0 (0%)
Do you recommend that radiographs be performed during follow-up visits?	No - Unless reinjury, continued pain, or complication occurs Yes - Once at first follow-up Yes - Once at end of treatment Yes - Multiple radiographs until fracture 'union'	12 (52.2%) 6 (26.1%) 3 (13.0%) 2 (8.7%)
When do you recommend full-time immobilization be discontinued?	Do not recommend any full-time immobilization 1-2 weeks 3-4 weeks 5-6 weeks >6 weeks	2 (8.7%) 2 (8.7%) 18 (78.3%) 1 (4.3%) 0 (0%)
When do you permit these patients to return to full activities (including sports)?	Do not place restrictions on return to activities 1-2 weeks 3-4 weeks 5-6 weeks >6 weeks	1 (4.3%) 0 (0%) 6 (26.1%) 14 (60.9%) 2 (8.7%)

Distribution of responses to buckle fracture management questions

**Table 3. Reported Barriers to Implementation of ‘Minimalist’ Practices**

Which of the following factors limit or would limit your utilization of a ‘minimalist’ approach to the management of buckle fractures of the wrist? (check all that apply)	n = 22
Family preferences for alternative treatment (i.e. cast)	13 (59.1%)
Lack of trust in patient compliance with splints	12 (54.5%)
Safety concerns	6 (27.4%)
Concerns regarding splint fit (i.e. patient arm size/shape)	4 (18.1%)
Confidence in appropriate patient selection	3 (13.6%)
Prior experiences in the management of buckle fractures	3 (13.6%)
*Lack of support for this practice from orthopaedic surgeon colleagues	2
*Family apprehension (told injury was more severe by another provider)	1
*Uncertainty of pediatrician comfort providing injury follow-up	1
Insufficient support of the literature	0 (0%)

Twenty-two providers reported on barriers influencing clinical decision-making. Results presented in rank order. A “\*” denotes a write-in response for which frequency percentages were not calculated as they were not options available for all respondents.

perceptions of other barriers are shown in Table 3. Among the influential factors studied, colleague opinion and patient and family preferences had the greatest influence on providers’ practice. Seventeen (77.2%) respondents were aware of the literature base supporting the use of minimalist strategies; however, evidence from the literature was the least influential of the studied variables on clinical decision-making. A summary of provider responses to influential factors is displayed in Table 4. After the survey, 6 (35.3%) of the providers not already using minimalist-type strategies stated they would change their practice while 9 (52.9%) would consider changing.

**Demographic Associations with ‘Minimalist’ Preferences**

The mean years of practice was greater among providers preferring the routine use of radiographs in follow-up (18.7 vs. 5.8 years,  $p = 0.035$ ). In addition, orthopaedic surgeons demonstrated a trend towards greater utilization of this practice when compared to their non-orthopaedic surgeon colleagues (83% vs. 35%,  $p = 0.069$ ). No associations were seen regarding physician training and years in practice when comparing preference for cast or splint immobilization.

**Table 4. Influences on Clinical Decision-Making**

Influencing Factor	Mean Rating (SD)
Colleague Influence	2.5 (1.2)
Patient/Caregiver Preference	2.5 (1.4)
Training	2.6 (1.3)
Personal Experience	3.4 (1.3)
Evidence from Literature	4.3 (0.98)

Perceptions of 20 providers on how influential certain factors were on their clinical decision-making. Items were rated on a scale from 1 to 5 with 1 being ‘most influential’ and 5 being ‘least influential’.

**DISCUSSION**

This survey provides novel insight into the decision-making process of a diverse group of clinicians caring for musculoskeletal injuries. Our findings demonstrate that the majority of providers at our institution caring for buckle fractures have a preference for traditional practices despite awareness of evidence supporting alternative measures. The survey also highlighted the perspectives of providers who do not predominantly care for children, which may be more representative of practices and perspectives outside of centers with numerous dedicated pediatric musculoskeletal providers. Lastly, we identified the significant influence that patients and their families have on the decision-making process, existing as an additional perceived barrier among providers to the implementation of minimalist practices.

**Actual versus Preferred Practice**

In establishing the basis for this survey study, this group examined practices in the management of buckle fractures at our institution from 2011-2014. This work identified a high rate of casting (93%) and frequent use of routine orthopaedic clinic follow-up and radiographic exams.<sup>10</sup> In the current study, conducted two years later, a diverse group of musculoskeletal providers indicated mixed opinions of these treatment options, still preferring traditional practice overall. However, findings did indicate greater favorability for minimalist measures than our prior study suggested. It is unclear whether this represents a true shift in opinion and practice, a change in treating providers, or simply reflects the reality of preferences not always translating perfectly into practice. Without established guidelines, these injuries can easily fall into the treatment algorithms of other forearm fractures, prompting more frequent clinical follow-up or radiographs that are unnecessary for safe and effective management.

Based on our survey results, removable immobilization was preferred in nearly half of providers, but still less



frequently than the cast alternative. Most providers advocated for some form of scheduled follow-up for these injuries, the majority of whom preferred a visit within 2 weeks. Only one provider expressed willingness to not require follow-up as long as the patient's pain resolves appropriately. Finally, despite the inherent stability of buckle fractures, nearly half of providers surveyed still felt some form of follow-up imaging was necessary, even if the patient demonstrates an expectant recovery. These findings suggest that the majority of providers remain beholden to traditional management and follow-up practices for this injury pattern.

### **Differences In Provider Opinions**

Increasing utilization of minimalist strategies in the management of pediatric buckle fractures of the distal forearm has been seen in some provider populations over the past two decades.<sup>12,16</sup> As the evidence base<sup>1-8</sup> evolves, we anticipate that this trend will continue. However, the findings of two surveys by Boutis et al. among pediatric orthopaedic<sup>11</sup> and EM<sup>12</sup> providers suggest that notable differences in utilization exist between some provider groups. First, utilization of removable immobilization in the United States appears to lag behind our Canadian neighbors (27.5% vs. 55% of providers). Additionally, their findings indicate that pediatric orthopedists overall appear less inclined to utilize this strategy as compared to EM providers (29.1% vs. 63.2%). Differences in utilization of removable devices were also seen when comparing general versus pediatric EM providers (75.8% vs. 55.0%). Although our survey methodology differed slightly, inquiring about individual provider rather than institution preferences, our survey of a mixed group of providers identified a preference for removable immobilization within these ranges (43.5% of providers). Unfortunately, our limited sample size did not permit provider subgroup comparisons of this preference.

In addition to the ease of application, removable immobilization in the management of buckle fractures of the distal forearm also permits flexibility in patient follow-up. Prior work indicates that routine follow-up imaging is unnecessary and some advocate for clinical follow-up being performed on an as needed basis.<sup>17,18</sup> Providers in our cohort were largely averse to the idea of no scheduled clinical follow. Prior work suggests EM providers are only slightly more accepting of this strategy, although most felt orthopaedic evaluation was not required and PCP follow-up was appropriate.<sup>12</sup> However, it should be noted that this previous work was performed among Canadian providers so differences with our cohort may be, in part, related to differences in our respective healthcare systems.

### **Barriers and Influences**

Interestingly, our findings indicate that the most commonly perceived barriers to utilizing minimalist strategies are both subjective and without a scientific basis: patient compliance concerns and patient and family preferences. Patient compliance concerns appear universal, with similar results seen in both provider surveys by Boutis et al.<sup>11,12</sup> Despite the frequency of reporting of this cited barrier, no evidence exist to date as to the validity of these concerns.

Despite a firm grasp on evidence-based measures, many providers remain strongly influenced by the preferences of patients and their families. And in general, this influence is perceived as a substantial barrier to the implementation of minimalist strategies as casting is perceived as superior. Although this experience is often verbalized by providers, our survey is the first to quantify this sentiment among a diverse group of clinicians. Some providers, with near equivalence of immobilization strategies, prefer to avoid the long discussions that may be required in order to sway a family towards a splint.

### **Limitations**

This survey-based assessment has multiple notable limitations. Although our response rate was high relative to most provider surveys, it remains subject to non-response bias. Additionally, a non-response analysis could not be performed due to methodological factors to assure anonymity. Individuals with little interest in the topic of buckle fractures who may not be aware or feel the evolving evidence is worthwhile or valid may be less likely to respond to a survey on the topic. Additionally, although the survey was dispensed in a deidentified manner, it was performed at a single institution and some may have been concerned about reporting characteristics that gave clue to their identity in some way (specialty or years in practice). Lastly, some may question the generalizability of the results, however, we feel this may in fact be both a strength and a limitation of the surveyed group of providers. While the results are likely not reflective of larger institutions where all children are managed solely by pediatric specialists, we do feel the results may capture management perspectives among a broad group of providers who are likely to be involved in the care of these injuries outside of these highly-specialized environments. We encourage other institutions to perform similar assessments to determine how pervasive these opinions truly are to enable changes in practice management.

### **Future Directions**

With a better understanding of provider decision-making enabled by this and other related studies, future

work should seek to deconstruct obstacles to implementation of minimalist strategy. Together, this work can assist quality improvement efforts at the local level and national campaigns such as Choosing Wisely<sup>19</sup> and guides from the National Institute for Health and Care Excellence (NICE)<sup>20</sup> to optimize the care of pediatric patients and their families.

### CONCLUSION

This study identified mixed perspectives regarding the preferred management of pediatric buckle fractures of the distal forearm among a diverse group of providers caring for musculoskeletal injury at a single institution. Despite growing evidence supporting minimalist strategies, providers remain split on preferred practices. Additionally, results indicated that colleague opinions and patient preferences carry more weight than the evidence base in influencing the management of this injury among the surveyed providers. Providers do appear willing to consider changes in practice, but concerns about patient compliance with removable immobilization and strong family preferences exist as significant barriers.

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## APPENDIX - Provider Survey

(\* = optional questions)

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### Section 1: Demographics

1. Years in practice\*
2. Job Title
  - a. MD/DO
  - b. PA
  - c. NP
3. If MD/DO → Training Specialty\*
  - a. Emergency Medicine
  - b. Family Medicine
  - c. Orthopaedic Surgery
  - d. Pediatrics
  - e. PM&R
4. How frequently do you care for pediatric patients in your practice?
  - a. Nearly Always (>75%)
  - b. Mostly (50-75%)
  - c. Sometimes (25-50%)
  - d. Almost Never (<25%)

### Section 2: Buckle Fracture Management

1. How do you prefer to immobilize pediatric buckle fractures of the wrist in the acute setting?
  - a. Splint
  - b. Cast
  - c. Soft Dressing
  - d. No Immobilization
2. When should these patients be seen in follow-up? .
  - a. 1-2 weeks
  - b. 3-4 weeks
  - c. 5-6 weeks
  - d. >6 weeks
  - e. Never unless re-injury, continued pain or complication occurs
3. Should radiographs be performed on follow-up?
  - a. Yes - Multiple radiographs until fracture healed
  - b. Yes - Once at first follow-up
  - c. Yes - Once at end of treatment
  - d. No - Unless reinjury, continued pain or complication occurs



## **APPENDIX - Provider Survey**

4. When should full-time immobilization be discontinued?
  - a. Do not recommend any full-time immobilization
  - b. 1-2 weeks
  - c. 3-4 weeks
  - d. 5-6 weeks
  - e. >6 weeks
5. When can patients return to full activities including sports?
  - a. Do not place restrictions on return to activities
  - b. 1-2 weeks
  - c. 3-4 weeks
  - d. 5-6 weeks
  - e. >6 weeks

### **Section 3 (cannot return to Section 2): Approach To Decision Making**

1. Are you aware that multiple large case series and randomized controlled studies support the use of a 'minimalist' approach to the management of buckle fractures consisting of removable splint immobilization at the time of injury with late (>3 weeks) or no recommended orthopaedic follow-up and no repeated radiographs (unless complication or reinjury occurs)? - This is not a test :-). We appreciate your honesty in answering this question.
  - a. Yes - I am aware of this literature
  - b. No - I am not familiar with this literature
2. If the above information is news to you, are you now amenable to altering your practice and instituting the 'minimalist' approach for appropriately selected patients with forearm buckle fractures in your practice?
  - a. Yes - I will change my practice now
  - b. No - I won't change my practice
  - c. Maybe - I will consider it
  - d. Not applicable - I already institute the 'minimalist' approach
3. Which of the following factors limit or would limit your utilization of a 'minimalist' approach to the management of buckle fractures of the wrist (Select all that apply)?
  - a. Safety concerns
  - b. Insufficient literature
  - c. Lack of trust in splint compliance
  - d. Concerns regarding patient fit (i.e. arm size/shape)
  - e. Prior experience with displacement of a buckle fracture
  - f. Family preference for alternate treatment
  - g. Confidence in appropriate patient selection
  - h. Other (open response)
4. On a 5 point scale, please rate the following factors on the amount of influence they have in selecting or altering your style of management in orthopaedics
  - a. Literature
  - b. Training
  - c. Personal experience
  - d. Colleague influence
  - e. Patient and caregiver preferences

# THE COST-EFFECTIVENESS OF REVERSE TOTAL SHOULDER ARTHROPLASTY VERSUS OPEN REDUCTION INTERNAL FIXATION FOR PROXIMAL HUMERUS FRACTURES IN THE ELDERLY

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## ABSTRACT

**Background:** Open reduction and internal fixation (ORIF) of proximal humerus fractures in elderly individuals (age >70) carries a relatively high short-term complication and reoperation rate but is generally durable once healed. Reverse total shoulder arthroplasty (RTSA) for fractures may be associated with superior short-term quality of life but carries the lifelong liabilities of joint replacement. The tradeoff between short and long-term risks, coupled with disparities in quality of life and cost, makes this clinical decision amenable to cost-effectiveness analysis.

**Methods:** A Markov state-transition model was constructed with a base case of a 75 year-old patient. Reoperation rates, quality of life values, mortality rates, and costs were based upon published literature. The model was run until all patients had died to simulate the accumulated costs and benefits.

**Results:** RTSA was associated with greater quality of life (7.11 QALYs) than ORIF (6.22 QALYs). RTSA was cost-effective with an incremental cost-effectiveness ratio of \$3,945/QALY and \$27,299/QALY from payor and hospital perspectives, respectively. RTSA was favored and cost-effective at any age above 65 and any Charlson Score. The model was sensitive to the utility of both procedures

**Conclusion:** RTSA resulted in a higher quality of life and was cost-effective in comparison to ORIF for elderly patients.

**Level of Evidence:** III

**Keywords:** proximal humerus fracture, open reduction and internal fixation, reverse total shoulder arthroplasty, cost-effectiveness

## INTRODUCTION

Proximal humerus fractures are common injuries in the elderly.<sup>1,3</sup> While the majority of these fractures are treated non-operatively, a small percentage are ultimately treated surgically.<sup>4</sup> Even when surgery has been decided upon, the choice of procedure is controversial. Surgical options have historically included hemiarthroplasty (HA) or open reduction and internal fixation (ORIF). A drawback of ORIF is a high reoperation rate ranging from 13%- 29%.<sup>5,6</sup> Causes of reoperation include hardware failure, screw cutout, nonunion, malunion, infection, and avascular necrosis requiring either removal or hardware, revision surgery, or a secondary arthroplasty.<sup>5,7</sup> Additionally, up to 16% of patients complain of long-term shoulder symptoms following ORIF.<sup>7</sup>

Reverse total shoulder arthroplasty (RTSA) is an increasingly popular option for proximal humerus fractures,<sup>8,10</sup> and RTSA has demonstrated superior clinical outcomes in comparison to HA.<sup>11-13</sup> Although RTSA-specific utility data is unavailable, quality of life scores demonstrate that HA results in superior outcomes, in comparison to ORIF, for addressing proximal humerus fractures in elderly patients,<sup>14,15</sup> possibly due to less pain.<sup>14</sup> It is reasonable to assume that these benefits also apply to RTSA since it has been shown to be superior to HA.<sup>11-13</sup> However, there are concerns regarding the lifelong risk of failure following any arthroplasty.<sup>16-18</sup>

Previous research has shown that RTSA is a cost-effective alternative to HA due to its superior function.<sup>19,20</sup> As the use of HA for proximal humerus fractures diminishes, the choice of surgical procedure for these injuries in elderly patients has principally come down to ORIF versus RTSA. However, the cost-effectiveness of RTSA versus ORIF is unknown. This question is worthwhile because primary RTSA is a more expensive procedure than ORIF,<sup>21</sup> and subsequent revision arthroplasty after failed ORIF is even more costly.<sup>22</sup> Additionally, the tradeoff between short and long-term risks, coupled with disparities in quality of life scores between procedures, makes decision modeling valuable. The objective of this study was to explore the decision between RTSA and

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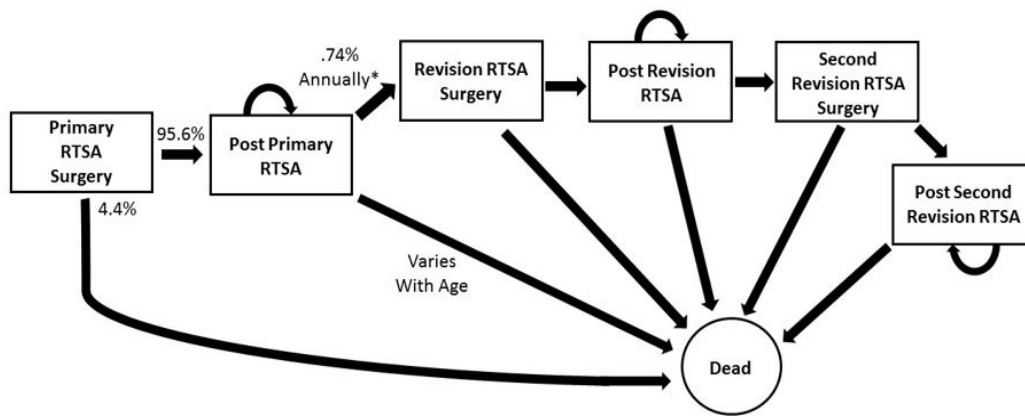


Figure 1. Reverse total shoulder arthroplasty portion of the Markov Model. Curved arrows indicate health states where patients remain indefinitely until a revision event or death. \*Annual RTSA revision rate doubled after 5 years (1.48%) and tripled after 10 years (2.22%).

ORIF for proximal humerus fractures in the elderly by using a Markov model to compare the accumulated costs and effectiveness of these two treatments.

### METHODS

We created a Markov transition state model to compare RTSA to ORIF for proximal humerus fractures, with a base case of a 75-year-old patient with a Charlson comorbidity score<sup>23</sup> of 1. Markov modeling makes it possible to quantify the costs and outcomes of a population stochastically transitioning through a series of health states and events.<sup>24</sup> We assumed that the fracture pattern was one that required surgery and was appropriate for either RTSA or ORIF. Markov modeling allowed all patients to initially undergo either an RTSA or ORIF before being distributed to mutually exclusive health states based upon appropriate literature-based probabilities. Each

health state and surgical procedure was associated with a literature-based cost and a quality adjusted life year (QALY) value.

The incremental cost-effectiveness ratio (ICER) was calculated by dividing the total difference in costs between the competing strategies by the difference in effectiveness of the strategies. A willingness to pay of \$100,000 per QALY was used throughout the model<sup>25</sup> in addition to a 3% annual discount for both costs and health utilities.<sup>19</sup> In the model, patients resided within a given health state for one year, similar to previous modeling studies,<sup>19</sup> and were only allowed to undergo surgery once per cycle. We cycled the model until all patients died to simulate the accumulated lifetime benefits and costs of each approach. All modeling was completed in TreeAge Pro 2018 (Williamstown, MA, USA).

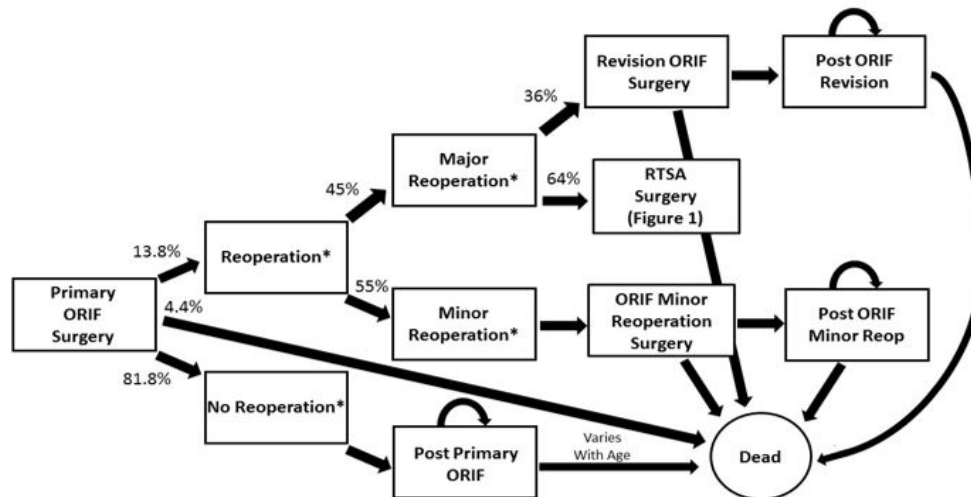


Figure 2: Open Reduction and Internal Fixation portion of the Markov Model. Curved arrows indicate health states where patients remain indefinitely until death. \*Indicates instantaneous chance nodes used to distribute patients based upon probabilities; these do not have a cost or quality of life value associated with them.

**Model**

In the models, all patients first underwent either primary RTSA or primary ORIF surgery (Figures 1 and 2). In the RTSA model, patients then transitioned to the Post Primary RTSA state if they survived the year following surgery. Patients would then remain in the Post Primary RTSA state until they either died or required a revision procedure (Table 1, Figure 1). Patients could undergo up to two revision procedures within the RTSA model. After the index ORIF procedure, patients passed through a series of instantaneous chance nodes to determine if they would require a reoperation. (Table 1, Figure 2). Reoperation options included Revision ORIF, RTSA, or a Minor Reoperation, with corresponding health states following each procedure. An assumption of the model was that ORIF patients would only undergo

a single reoperation. Patients who underwent RTSA as their revision surgery were transitioned to a Post Primary RTSA health state post-operatively that then connected with nodes representing RTSA success, failure and revision that were identical to the RTSA model. The model did not consider revision to HA as an option for patients with a failed RTSA.

**ORIF Reoperations**

The baseline reoperation rate for the ORIF group, 13.8% (Table 1), was based upon a systematic review of locking plate fixation for proximal humerus fractures based upon 514 patients in 12 studies.<sup>26</sup> In this study the average patient age was 62 years, and 45% of fractures were 3-part, 34% 4-part, and 21% 2-part, with an average of 29.2 months follow-up. Because the range of reoperation

**Table 1 : Baseline Probabilities Used in the Model**

Variables	Probability	Source
<b>Open Reduction and Internal Fixation (ORIF)</b>		
Risk of Reoperation	13.8%	5, 7, 26-30, 46, 47
Risk of Major Reoperation (If requiring a Reoperation)%	45%	5, 7, 27-30
Risk of Arthroplasty (If requiring a Major Reoperation)*	64%	5, 7, 27-30
<b>Reverse Total Shoulder Arthroplasty (RTSA)</b>		
Annual Probability of Primary RTSA Failure (Years 1-5)	0.74%	16, 18
Annual Probability of Primary RTSA Failure (Years 6-10)	1.48%	31, 32
Annual Probability of Primary RTSA Failure (Years 11+)	2.22%	Assumption (3x rate of early revision of primary RTSA)
Annual Probability of Revision RTSA Failure (Years 1-5)	2.00%	33, 34
Annual Probability of Revision RTSA Failure (Years 6-10)	4.00%	Assumption (2x rate of early revision of revision RTSA)
Annual Probability of Revision RTSA Failure (Years 11+)	6.00%	Assumption (3x rate of early revision of revision RTSA)
Annual Probability of Second Revision Failure (Per Year)	4.00%	Assumption
<b>Mortality</b>		
Annual CDC Life Table Mortality Values (Base)	Varies	35
Osteoporotic Fx Mortality Increase (5-years)	1.5 X Base	36
Charlson Score 0	0.5 X Base	23, 37, 38
Charlson Score 1	Base	23, 37, 38
Charlson Score 2	1.5 X Base	23, 37, 38
Charlson Score 3+	2.0 X Base	23, 37, 38

\*Percentage of all reoperations assumed to be, "Major". Major reoperations were defined as either revision ORIF or Arthroplasty.

†Percentage of all major reoperations assumed to be, "Arthroplasty". In the analysis, all arthroplasty surgeries were modeled to be reverse total shoulder procedures.



rates in the literature is wide, for this study we performed a sensitivity analysis on the reoperation rate.<sup>7,27</sup>

When determining probabilities, a revision ORIF procedure, HA, or RTSA procedure were considered major reoperations. Simple hardware removal or screw exchange, a biceps tendon procedure, and shoulder arthroscopy were all considered minor reoperations. If a patient underwent both a minor and major reoperation, they were grouped into the major reoperation group since they could only undergo revision surgery once in the model. Studies evaluating these outcomes were identified by reviewing references from a PUBMED search, and all identified studies with relevant data points were included in each calculation when applicable. The probability of a major reoperation ranged from 28.6% to 91.7% in the literature.<sup>5,7,28,29</sup> A weighted average of published values, based upon the number of patients included in each study,<sup>5,7,27-30</sup> was calculated to obtain a base case probability of 45% for major surgery in the portion of patients requiring a reoperation. When considering the probability of utilizing arthroplasty versus revision ORIF to address primary ORIF failure, published values ranged from 50% to 100%.<sup>5,7,29,30</sup> A weighted average of published values<sup>5,7,27-30</sup> was used to obtain a base case probability of arthroplasty of 64% in patients undergoing major revision surgery and it was assumed that all patients in this branch underwent RTSA, in the model.

### RTSA Failure

Short-term (5-year) failure rates of RTSA were derived from a registry study of 565 prostheses used to treat fractures (average age of 77 years old),<sup>18</sup> and from a retrospective cohort study in which 218 patients underwent RTSA for fracture (average age of 78 years old).<sup>16</sup> A weighted average annual probability of failure of 0.0074 (Table 1) was used as the base case based upon the probability of 0.0080 from the registry study,<sup>18</sup> and 0.0058<sup>16</sup> from the cohort study. Failure rates at 10-years were provided by a study of 80 prostheses that demonstrated a 9% failure rate at 10 years (0.0090 annual probability) in patients who underwent RTSA for a variety of indications,<sup>31</sup> in addition to a study of 191 prostheses that demonstrated a 7% failure rate at 10 year of follow up (0.0070 annual probability) in patients who underwent RTSA for rotator cuff pathologies.<sup>32</sup> Based upon these studies, and to conservatively account for increasing arthroplasty failure rates with time, the baseline RTSA failure rate was doubled during post-operative years 6-10 and tripled at 11 years. Prior literature demonstrated that revision RTSA prostheses fail at rates generally higher than primary RTSA,<sup>33,34</sup> so an annual probability of revision failure of 0.02 (2.7x primary RTSA failure rate) was used for the

first 5-years post-operatively, and then doubled between years 6-10, and tripled at 11 years.

### Mortality

Baseline annual mortality according to age was derived from the Center for Disease Control Mortality Tables (Table 1).<sup>35</sup> Patients were assumed to have a 1.5-times increase in their risk of death for 5 years following their fracture due to the long-term mortality associated with osteoporotic fractures.<sup>36</sup> The impact of the Charlson Comorbidity score was accounted by first assuming an average score of 1 in the general population.<sup>37</sup> A Charlson score of 0 was associated with 0.5-times lower annual mortality, a score of 2 with 1.5-times higher mortality, and a score of 3 and above with a 2.0-time higher mortality.<sup>23,38</sup>

### Costs

The costs of both ORIF and RTSA were extracted from a study which reported the average Medicare reimbursements and hospital charges for the procedures (Table 2).<sup>21</sup> Revision procedures were assumed to be 1.4-times the costs of primary procedures consistent with previous literature quantifying these differences in knee arthroplasty.<sup>22</sup> A minor ORIF reoperation was assumed to be half the cost of a primary ORIF as no inpatient stay nor implants would be required. All costs were adjusted to 2018 values using the consumer price index.<sup>39</sup>

**Table 2. Baseline Costs and Utilities Used in the Model**

Variables	Value	Source
<b>Costs</b>		
Primary ORIF to Payor	\$12,986	21
Primary ORIF to Hospital	\$66,706	21
Revision ORIF to Payor	\$18,180	21, 22
Revision ORIF to Hospital	\$93,388	21, 22
Minor Reoperation Post-ORIF to Payor	\$6,493	Assumption
Minor Reoperation Post-ORIF to Hospital	\$33,353	Assumption
Primary RTSA to Payor	\$15,720	21
Primary RTSA to Hospital	\$86,390	21
Revision RTSA to Payor	\$22,008	21, 22
Revision RTSA to Hospital	\$120,946	21, 22
<b>Utility of Health States (QALYs)</b>		
Post Primary ORIF	0.70	15, 40
Post Primary RTSA	0.81	14
Post ORIF Minor Reoperation	0.65	Assumption
Post ORIF Revision	0.60	Assumption
Post RTSA Revision	0.69	33, 34
Post Second Revision RTSA	0.59	Assumption
Undergoing Major Surgery (Year of Surgery)	0.55	Assumption

**Table 3. The Cost-Effectiveness of ORIF vs. RTSA**

	Accrued Costs (US Dollars)	Incremental Costs	Accrued Quality Adjusted Life Years (QALYs)	Incremental (QALYs)	Incremental Cost- Effectiveness Ratio (ICER)
<b>Payor Perspective</b>					
Open Reduction and Internal Fixation (ORIF)	\$14,523	-	6.22	-	-
Reverse Total Shoulder Arthroplasty (RTSA)	\$17,959	\$3,435	7.11	0.89	3,871
<b>Hospital Perspective</b>					
Open Reduction and Internal Fixation (ORIF)	\$74,827	-	6.22	-	-
Reverse Total Shoulder Arthroplasty (RTSA)	\$98,693	\$23,866	7.11	0.89	26,894

**Utilities**

A quality of life value, in the form of an EQ-5D index score of 0.70 (Table 1), was reported for ORIF patients as part of a randomized control trial comparing operative fixation to non-operative management in geriatric patients with proximal humerus fractures, and was used in the model as the QALYs associated with ORIF.<sup>15</sup> A similar EQ5-D value of 0.68 for ORIF patients was reported in a related prospective study.<sup>40</sup> Olerud et al. also reported an average EQ-5D score of 0.81 for hemiarthroplasty patients as part of a similar randomized control trial comparing HA to non-operative treatment in geriatric patients with proximal humerus fractures.<sup>14</sup> This hemiarthroplasty utility value (0.81 QALYs) was applied to patients undergoing RTSA in our model because there was no data specifically available for RTSA in the literature. There is ample evidence that RTSA shoulder function is superior to that of

hemiarthroplasty for the treatment of proximal humerus fractures, so using the utility value for hemiarthroplasty here is conservative, and, if anything, underestimates the utility of RTSA in this study.<sup>13</sup> Prior research demonstrated an average decrease of 14.5% in the constant score following RTSA revision,<sup>11,33,34</sup> and this disutility was applied to both revision RTSA and ORIF procedures.

**Sensitivity Analyses**

One-way sensitivity analyses were completed for all cost and probability inputs across a range of clinically feasible values. Additional two-way sensitivity analyses were completed for the utility values the costs associated with the procedures.

**RESULTS**

In the base case scenario of a 75-year-old patient with a Charlson score of 1, RTSA provided superior lifetime effectiveness (7.11 QALYs) in comparison to ORIF (6.22 QALYs; Table 3). Total lifetime accrued costs with ORIF were \$14,478 and \$74,604 from the perspective of the payor and hospital respectively. Total lifetime accrued costs with RTSA were \$17,959 and \$98,693 from the perspective of the payor and hospital respectively. Based upon these differences, RTSA was cost-effective from the standpoint of both the payor and hospital with ICERs of \$3,945/QALY and \$27,299/QALY respectively (Table 3). The ICER remained generally stable across age groups with the exception of notably higher ICERs in older patients with multiple comorbidities (Table 4). The effect of patient comorbidities was variable with the healthiest patients demonstrating higher ICERs at age 65, but lower ICERs at age 85.

Sensitivity analyses demonstrated that RTSA was cost effective at any age above 65 and any comorbidity score from the standpoint of the payor, but that at age

**Table 4. The Impact of Patient Age and Charlson Comorbidity Score on Cost-Effectiveness**

Age	Charlson Score	RTSA Incremental Cost Effectiveness Ratio (ICER) Payor Perspective (\$/QALY)	RTSA Incremental Cost Effectiveness Ratio (ICER) Hospital Perspective (\$/QALY)
65 years old	0	4,727	29,319
	1	4,260	27,343
	2	4,063	26,798
	3≤	3,963	26,772
75 years old	0	4,156	27,097
	1	3,871	26,894
	2	3,900	28,376
	3≤	4,064	30,622
85 years old	0	4,003	28,531
	1	4,536	35,505
	2	5,741	46,569
	3≤	7,438	60,899

**Table 5. Sensitivity Analyses of Included Variables**

Variable	Base	Low	High	Payor Threshold	Hospital Threshold
<b>Patient Characteristics</b>					
Age (years)	75	65	100	--	97
Charlson Score	1	0	3	--	--
<b>Probabilities</b>					
ORIF Probability of Reoperation	.138	0	1	--	--
ORIF Probability of Major Reoperation (vs. minor)	.482	0	1	--	--
ORIF Probability of RTSA (vs. revision ORIF)	.57	0	1	--	--
RTSA Annual Probability of Failure (Baseline)	.74%	0	25%	22%	5.1%
Revision RTSA Annual Probability of Failure (Baseline)	2.0%	0	25%	--	--
<b>Utilities</b>					
Utility of Primary ORIF (QALYs)	0.70	0	1	0.80	0.78
Utility of ORIF Revision (QALYs)	0.60	0	1	--	--
Utility of Primary ORIF vs. Utility of Primary RTSA (Ratio)	0.86	0	1	0.99	0.96
Utility of Primary RTSA (QALYs)	0.81	0	1	0.70	0.73
Utility of RTSA Revision (QALYs)	0.69	0	1	--	--
Utility of Major Surgery (QALYs)	0.55	0	1	--	--
<b>Costs</b>					
Cost of Primary ORIF	\$12,986/\$66,706	0	100,000	--	<\$6,089
Cost of ORIF Revision	\$18,180/\$93,388	0	100,000	--	--
Cost of ORIF Minor Reoperation	\$6,493/ \$33,353	0	50,000	--	--
Cost of Primary RTSA	\$15,720/\$86,390	0	200,000	\$93,084	\$145,226
Cost of Revision RTSA	\$22,008/ \$120,946	0	200,000	--	--

97 the procedure was no longer cost-effective from the standpoint of the hospital (Table 5). The RTSA was cost-effective at any ORIF failure rate but was not cost-effective if the annual RTSA failure rate exceeded 22% or 5.1% from the standpoint of payor and hospital respectively. If the utility of ORIF increased to 0.80 (payor) or 0.78 (hospital) then it was the preferred procedure from a cost-effectiveness perspective. Similarly, if the utility of RTSA decreased to 0.71 (payor) or 0.73 (hospital) then ORIF was favored. Altogether, if the relative utility of ORIF in comparison to RTSA was 99% (payor) or 96% (hospital), then it was the preferred surgery. Finally, if the cost of RTSA exceeded \$92,732 (payor) or \$144,678 (hospital), it was no longer cost-effective. Two-way sensitivity analyses simultaneously varying either the utility values or costs of the procedures demonstrated that the conclusions of the model from the standpoint of the hospital were sensitive to these changes (Figures 3 and 4).

**DISCUSSION**

Arthroplasty and ORIF are the two major surgical interventions available for the treatment of geriatric proximal humerus fractures. Open reduction and internal fixation has been historically marked by higher initial complication rates, particularly in older patients with poor bone quality while, while HA has also been marked by poor functional outcomes,<sup>41-44</sup> and long term

complications.<sup>45</sup> RTSA is a relatively recent alternative for treating proximal humerus fractures that offers superior patient outcomes in comparison to HA in this age group.<sup>11</sup> With the increased function provided by RTSA<sup>11</sup> and the general pain relief afforded by arthroplasty,<sup>14</sup> it is reasonable to consider the cost-effectiveness of RTSA versus ORIF for surgical proximal humerus fractures. Our evidence-based Markov model demonstrated that the accumulated quality of life associated with RTSA was greater than ORIF, and that this difference was cost-effective in patients aged 65 and above with any Charlson Comorbidity score. Overall, these findings highlight that the lower short-term reoperation rate and pain relief associated with RTSA outweigh the long-term risk of arthroplasty failure, despite the increased initial cost of RTSA, which makes RTSA a cost-effective option for maximizing outcomes.

Previous literature has highlighted that RTSA is cost-effective in comparison to both non-operative treatment and HA for the treatment of proximal humerus fractures,<sup>19</sup> but its effectiveness relative to ORIF is unknown. This study included a utility of 0.85 for RTSA versus 0.81 for HA, a value higher than the 0.81 QALYs used for RTSA in our study, based on the assumption that higher clinical scores with RTSA equate to a measurable increase in quality of life.<sup>19</sup> In order to conservatively estimate the effectiveness of RTSA we assigned it a utility equivalent

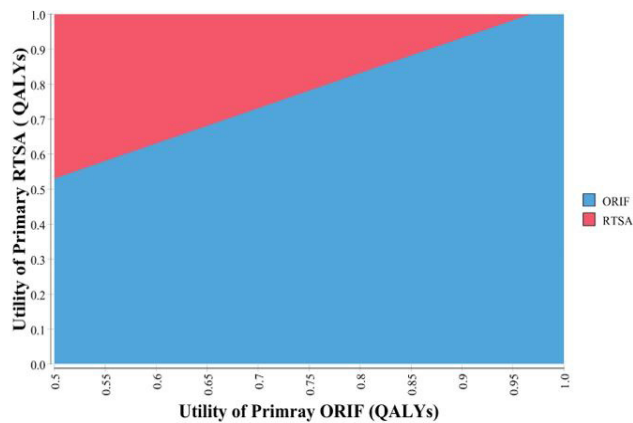


Figure 3: Two-way sensitivity analysis of the quality of life associated with the two procedures. The conclusions of the model varied based upon the utility values assigned to each procedure.

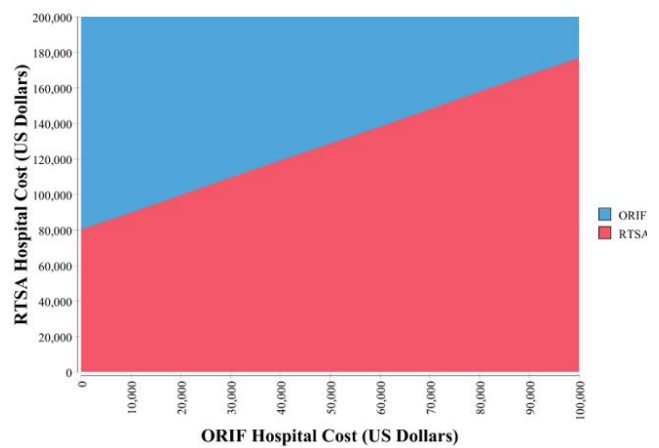


Figure 4. Two-way sensitivity analysis of the costs associated with the two procedures from the standpoint of the hospital. The conclusions of the model varied based upon the costs assigned to each procedure.

to that previously published for HA, which is conservative given the likely higher utility of RTSA because of its improved pain and function compared to HA. This estimate would err on the side underestimating the utility of RTSA and potentially favor ORIF. If indeed the increased function associated with RTSA results in a better quality of life, it may be preferred even more over ORIF.

Sensitivity analyses demonstrated that RTSA was cost-effective across the range of plausible probabilities tested but was sensitive to the quality of life inputs. With large variation in the published rates of reoperation after ORIF,<sup>5,7,27-30,46-48</sup> it was important to see that the superiority of RTSA was robust. Similarly, the superiority of RTSA was not influenced by varying the annual primary or revision failure rate across clinically reasonable probabilities. Although a threshold was present for the annual primary RTSA failure rate for both the payor (22%) and hospital (5.1%), these values are well above published failure rates.<sup>16,18</sup> Analysis demonstrated that the model was sensitive to the utility values, and suggested that ORIF was favored if its effectiveness exceeded 99% (payor) or 96% (hospital) that of RTSA. The values used in our study were extracted EQ5-D index scores from a set of related randomized control trials comparing ORIF<sup>15</sup> and HA<sup>14</sup> to non-operative treatment, and as mentioned previously, we conservatively utilized the value associated with HA for RTSA. The average age of the patients in the referenced studies was 74 and 77, and it is important to consider that utility values may be lower in higher-demand, younger patients. Additionally, many surgeons consider strenuous upper-extremity activities to be a contraindication for RTSA, highlighting how patient variables play an important role in decision making. Another limitation of our model is that it did not consider non-operative management for these fractures, and instead assumed that decision to pursue some type of operative treatment had

already been made. While there are some injury patterns types which nearly always require surgery, such as a fracture-dislocation, conservative management is often at least a consideration for most patients and fracture patterns. Future studies are needed to compare the outcomes, and subsequent cost-effectiveness, of operative versus non-operative treatment of proximal humerus fractures in patients over age 70. Finally, our model was sensitive to the costs of RTSA, although the calculated threshold was well above current values.<sup>21</sup>

This study was limited by the lack of high-quality utility values for the ORIF and RTSA procedures, as these values affected conclusions. The literature sources used were modest randomized control trials of geriatric patients with proximal humerus fractures.<sup>14,15</sup> Although the cohorts were similar in age, they may have been drawing from different patient populations. Additional studies analyzing the relative effectiveness of these procedures at different ages and functional levels are necessary. Similarly, the role of injury-specific parameters, such as the fracture pattern, and patient-specific variables, such as the quality of the bone, need to be further studied. These factors could influence our cost-effectiveness model, and additional studies are needed to provide the necessary data for completing a more stratified decision-analysis. Additionally, high-quality registry data to predict failure rates in RTSA beyond 5-years is also lacking. Although our model was generally insensitive to these values, future studies examining the long-term failure rates of these prostheses are necessary. Furthermore, as with any model, we were forced to make assumptions within our model that cannot perfectly mirror the clinical path of all patients. Finally, the overall implications of our study must be kept in perspective due the lack of high-quality evidence underlying the results. While our analysis demonstrates that RTSA is a cost-effective option for



treating geriatric proximal humerus fractures, the data is not robust or nuanced enough to suggest that it is a superior option for all patients or circumstances. Instead, our analysis provides an additional lens for surgeons considering the costs and outcomes associated with this decision point.

While cost should certainly not be the primary factor influencing choice of surgical procedure, in the current medical environment of escalating costs and limited resources, it is a consideration in fracture management, and this study suggests that the higher cost of RTSA should not be a barrier to its utilization in the elderly proximal humerus fracture patient. The Markov model demonstrated that despite increased initial cost, RTSA resulted in a higher quality of life and was cost-effective in comparison to ORIF for geriatric proximal humerus fractures. RTSA was favored due to the unpredictable results and relatively high rate of complications with ORIF, as well as the costs and decreased quality of life associated with revision operations. Future studies are needed for further delineate the quality of life values associated with each procedure as the results of the model were sensitive to these parameters.

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# SEX DIFFERENCE IN CONTUSION OF THE MEDIAL FEMORAL CONDYLE RIM-ASSOCIATION WITH MRI OCCULT MENISCAL TEARS IN THE ACL DEFICIENT KNEE

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## ABSTRACT

**Background:** Meniscal tears, specifically lateral meniscal tears, have a larger than expected underdiagnosis rate in the presence of an ACL tear. The purpose of our study was to search for an MRI bone contusion pattern associated with MRI occult meniscal tears in patients with an ACL tear, specifically a contusion of the rim of the medial femoral condyle (RMFC). Our hypothesis was that there would be a significant association between RMFC contusions and MRI occult meniscal tears in patients with an ACL tear. We also searched for a difference between sexes with respect to the presence of the RMFC contusion in the setting of an occult meniscal tear. We also categorized the type, size, and location of these occult meniscal tears in the setting of an ACL tear.

**Methods:** This was a retrospective study that examined characteristics of occult meniscal tears and their association with a RMFC bone contusion. IRB approval was obtained. The date range of the study was June 2009 through December 2015. 6392 consecutive knee MRI reports in patients with an ACL deficient knee were reviewed. The study group included 22 patients with MRI occult meniscal tears, the control group included 110 patients. Relevant statistical values were calculated.

**Results:** The most common type of occult meniscal tears were small radial and small longitudinal tears of the lateral meniscus. Occult meniscal tears were associated with an RMFC contusion in the study group ( $p=0.0457$ ), particularly in males ( $p = 0.0003$ ). In males with a torn ACL, the sensitivity of an RMFC contusion for an occult meniscal tear was 80%.

**Conclusion:** In males with an ACL tear, there

was a significant association between a contusion of the RMFC and an occult meniscal tear (commonly small radial or small peripheral partial-thickness longitudinal tears). RMFC contusions were reliably identified by radiologists in this study.

**Level of Evidence:** II

**Keywords:** knee, MRI, meniscus, bone contusion, anterior cruciate ligament

## INTRODUCTION

On knee MRI, meniscal tears, specifically lateral meniscal tears, have a lower than expected sensitivity in the presence of an anterior cruciate ligament (ACL) tear.<sup>1,2,3</sup> It has been previously shown that there is a marked decrease in magnetic resonance imaging (MRI) sensitivity, by as much as 25% in some studies, for lateral meniscal tears when an ACL tear is present.<sup>1</sup> It is standard practice to meticulously search for peripheral tears in the posterior horn of the lateral meniscus when an ACL tear is present; however, these tears are still missed or unable to be seen on MRI images.<sup>1,2,3</sup> At present, it is not well understood what percentage of missed lateral meniscal tears are due to an MRI occult tear versus human error. A previous smaller study with only six MRI occult lateral meniscal tears reported that only 10% (6 out of 59) of false negative lateral meniscal tears on MRI were due to an MRI occult tear. An MRI occult tear is defined as a tear that is found at surgery, but cannot be seen on MRI even after retrospective review of the MR images.<sup>2</sup> In addition, it has been reported that MRI occult meniscal tears most commonly occur in the posterior horn of the lateral meniscus in patients with an ACL tear.<sup>2</sup> To help ensure that all potential knee pathology is addressed during surgery, discovering a secondary MRI finding that one could use to indicate a high likelihood of an occult meniscal tear would be useful.

Individual bone contusions have been shown to be associated with MRI visible meniscal tears with no discrepancy between sexes.<sup>4,5</sup> A previous report, which did not separately evaluate males and females, showed no association between any bone contusion patterns and occult meniscal tears in patients with an ACL tear; however, it did find that a bone contusion of the rim of the medial femoral condyle (RMFC) was nearly significantly associated with MRI occult meniscal tears ( $p$ -value between

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Figure 1. 32-year-old male with an MRI occult meniscal tear that had a bone contusion of the rim of the medial femoral condyle (white arrow).

0.05 and 1.00).<sup>4</sup> One of the individual bone contusions commonly associated with an ACL tear, the RMFC, has been previously described in the literature as being seen when MRI meniscal tears are present in the ACL deficient knee (Figure 1).<sup>4,6</sup>

In order to discover a secondary MRI finding that would be useful in predicting the likelihood of an MRI occult meniscal tear, the purpose of our study was to determine if the association between RMFC bone contusions and MRI occult meniscal tears in the ACL deficient knee was affected by patient sex since there are prior reports of sex differences in factors that contribute to an acute ACL rupture with and without concomitant meniscal tear.<sup>7,8,9,10</sup> We hypothesize that the association between RMFC and MRI occult meniscal tear would be significant in only male patients. On average, since greater anterior translational forces are generated in the female knee during ACL injury from a pivot shift mechanism, the same mechanism that results in an RMFC bone contusion, we hypothesize that males are more likely to have an MRI occult meniscal tear (due to lower energy) in the specific setting of a concomitant ACL rupture and RMFC bone contusion and that this association would only be significant in males.<sup>6,9</sup> Also, we sought to determine the type, size, and location of MRI occult meniscal tears.

## METHODS

This was a retrospective study determining the location, type, and size of MRI occult tears (in patients with a concomitant ACL tear) and examining the association between occult meniscal tears with a RMFC and patient sex. The date range of the study was from June 2009 through December 2015 and consisted initially of 6392 consecutive patients with knee surgery and a knee MRI.

## Study Group

The study group consisted of patients with occult meniscal tears. An occult meniscal tear was defined as an operatively reported meniscal tear that was not visible on the MRI images, even when the MRI images were retrospectively reviewed.<sup>2</sup> The criteria for the study group were no prior knee surgery before the knee MRI, knee surgery at our institution within six months of the MRI, the presence of an ACL tear both by the surgical report and the MRI report, the presence of a meniscal tear in the surgical report, and an occult meniscal tear on MRI. The starting number of 795 patients are those patients with an ACL tear reported in both the MRI report and the corresponding surgical report from the ACL reconstruction. There were five exclusions consisting of one patient with greater than 6 months between the MRI and surgery and four patients with a history of prior knee surgery. After this, the clinical MRI radiology reports were reviewed. This yielded 74 patients that had a meniscal tear mentioned in the surgical report that was not mentioned in the clinical MRI radiology report.

In order to identify those patients with an MRI occult meniscal tear, a retrospective radiologist review was done by three board certified, fellowship trained musculoskeletal radiologists (DB, HO, KO), whose practice is 100% musculoskeletal radiology. Each radiologist independently reviewed the MRI images from the seventy-four patients with a missed meniscal tear to identify any occult tears. During this review, previously reported criteria for diagnosing a meniscal tear were used.<sup>2,11</sup> All three radiologists were blind to patient information and were told to evaluate each MRI for the type and location of meniscal tears. If any of the three radiologists diagnosed a meniscal tear that matched the description in the surgical report, the meniscal tear was not considered occult and the case was not included in the study group. This review yielded 22 patients with an MRI occult meniscal tear.

The MRI studies of the twenty-two occult tear cases were then reviewed independently, with no collaboration allowed, by the three previously mentioned radiologists for a RMFC bone contusion (Figure 1). Bone contusions were defined as geographic regions of abnormal signal intensity: low signal intensity on T1-weighted images and high signal intensity on fat-suppressed FSE T2-weighted images. A majority rules system was used, meaning a contusion was considered to be present if at least two of the three radiologists identified a RMFC bone contusion.

Next, the surgical reports for these twenty-two patients with MRI occult meniscal tears were reviewed and the size, location, and type of MRI occult meniscal tear was recorded.

### **Control Group**

From the 790 original cases, 110 control cases with known ACL tears were collected consecutively from November 2009 through October 2012 with the start date of November 2009 randomly selected excluding the previously described 5 patients who did not meet the inclusion criteria and excluding the 22 patients with an occult meniscal tear. The size of the control group was determined based on the typical size of control or study groups in prior publications on MRI accuracy for meniscal tears in the setting of an ACL tear. The three radiologists were again blind to any results or information and were asked to evaluate for the presence of a RMFC bone contusion on each knee MRI using the same method as with the study group cases.

### **MRI Imaging**

MRI examinations were performed at our institution using a 1.5 T superconducting magnet (Avanto, Siemens Healthcare) and a dedicated knee phased array extremity coil. FSE proton density-weighted and fat-suppressed FSE T2-weighted sequences were performed in a sagittal plane (lined up with the ACL). Fat-suppressed FSE T2-weighted sequences were performed in coronal and axial planes. A SE T1-weighted sequence was performed in the coronal plane. The FSE proton density-weighted parameters were: Number of Excitations (NEX)=1; TR/TE, 2230/28; echo-train length, 3; matrix, 320 x 320; field of view, 14 cm; and slice thickness, 2.5 mm. The sagittally oriented fat-suppressed FSE T2-weighted sequence parameters were: NEX=1; TR/TE, 6330/62; echo-train length, 11; matrix, 256 x 256; field of view, 14 cm; and slice thickness, 2.5 mm. The coronally oriented fat-suppressed FSE T2-weighted sequence parameters were: NEX=1; TR/TE, 4830/67; echo-train length, 11; matrix, 256 x 256; field of view, 14 cm; and slice thickness, 2.5 mm. The axially oriented fat-suppressed FSE T2-weighted sequence parameters were: NEX=1; TR/TE, 4870/59; echo-train length, 7; matrix, 256 x 256; field of view, 14 cm, and slice thickness, 3.0 mm. The coronally oriented SE T1-weighted sequence parameters were: NEX=1; TR/TE, 652/20; matrix 256 x 256; field of view, 14 cm; and slice thickness, 2.5 mm.

### **Statistical Analysis**

The sensitivity, specificity, positive likelihood ratio, positive predictive value, negative likelihood ratio, negative predictive value, and prevalence were calculated as data allowed or indicated. Cohen's kappa was calculated to assess inter-radiologist agreement for the presence of an RMFC bone contusion. Fisher's Exact Test was used to evaluate for statistical significance of the RMFC contusion between the study group (MRI occult meniscal

tears) and the control group, between males in both the study and control groups, and between females in both the study and control groups. Fisher's Exact Test was used to evaluate for statistical significance of sex distribution between the study group and control group. Fisher's Exact Test was used in the above scenarios given the number of patients and since the data are dichotomous nominal data. The student t-test was used to determine statistical significance in age between the study group and the control group. P-values of < 0.05 were statistically significant.

This study was reviewed and approved by our Institutional Review Board (IRB). Informed consent was waived by the IRB. The study was HIPAA compliant, no registries were used, and the patients were not part of a previously reported study.

### **RESULTS**

Of the 790 knees with an acute ACL tear by surgery, 386 torn medial menisci were identified and 330 torn lateral menisci were identified by surgery. For the medial menisci, review of the radiology reports yielded results of 373 true positive, 389 true negative, 15 false positive, and 13 false negative torn menisci. For the medial meniscus this yielded a sensitivity of 96.6% (94.3% - 98.2%), specificity of 96.3% (94.0% - 97.9%), positive likelihood ratio of 26.0 (15.8 - 42.8), positive predictive value of 96.1% (93.8% - 97.6%), negative likelihood ratio of 0.03 (0.02 - 0.06), negative predictive value of 96.8% (94.6% - 98%), and disease prevalence of 48.9% (45.3% - 52.4%). For the lateral menisci, review of the radiology reports yielded results of 269 true positive, 436 true negative, 24 false positive, and 61 false negative torn menisci. For the lateral meniscus this yielded a sensitivity of 81.5% (76.9% - 85.6%), specificity of 94.8% (92.3% - 96.6%), positive likelihood ratio of 15.62 (10.55- 23.14), positive predictive value of 91.8% (88.3% - 94.3%), negative likelihood ratio of 0.20 (0.16 - 0.24), negative predictive value of 87.7% (85.1% - 90.0%), and disease prevalence of 41.8% (38.3% - 45.3%). Note that the values in the above parentheses are the 95% confidence intervals.

The number of discrete tears in each meniscus is listed in Table 1. This number was higher than the number of torn menisci since some menisci had greater than one discrete tear visualized at surgery. The highest attainable sensitivity for detecting a meniscal tear in the control group, assuming no human error was present, that is, after the removal of the twenty-two cases where no tear could be seen on MRI even after review, is reported in Table 2.

Table 3 lists the size, location, and type of meniscal tear for the 22 occult tears. Radial (9/22 or 41%) and longitudinal (10/22 or 45%) tears accounted for the majority of the occult tears (16/22 or 82%). Nearly all the occult tears, 20 of 22 (90.9%), were tears of the lateral meniscus.

**Table 1. Meniscal Tear Details in Knees with an Anterior Cruciate Ligament Tear Prior to Radiologist Rereview**

Location of tear	Total menisci	Intact menisci at surgery	Torn menisci at surgery	Missed torn menisci by MRI	MRI sensitivity for meniscal tear	Total discrete tears at surgery	Missed discrete tears by MRI	Discrete tear sensitivity
Lateral meniscus	790	455	335	61	81.5	355	61	82.8
Medial meniscus	790	404	386	13	96.6	401	13	96.7
Total	1580	859	721	74	89.7	756	74	90.2

The remaining two were MRI occult tears of the medial meniscus.

Cohen's kappa was calculated to assess agreement between the radiologists for the presence of an RMFC bone contusion in the occult tear group. Kappa value between radiologists 1 and 2 was 0.61. Kappa value between radiologists 1 and 3 was 0.91. Kappa value between radiologists 2 and 3 was 0.72. These values are consistent with substantial agreement between the radiologists.

Table 4 displays the results for evaluation of the RMFC contusion as a predictor of an occult meniscal tear using the majority rules system after evaluation by the three radiologists. There was a statistically significant difference (p-value < 0.008) between males and females as to whether an RMFC bone contusion was found in association with an occult meniscal tear (see Table 4, column 1, and rows 3 and 4) with an RMFC bone contusion being found much more frequently in males with an MRI occult meniscal tear. That is, there is a statistically significant difference in that males are more likely to have an MRI occult meniscal tear with a RMFC bone contusion and concomitant ACL tear than females.

The p-value for sex between the occult and the control group was 0.15. The p-value for age between the occult and the control group was 0.33.

The sensitivity for an RMFC contusion identifying an occult meniscal tear for both sexes combined, for males,

and for females was 45.5% (10/22), 80.0% (8/10), and 16.7% (2/12) respectively (see Table 5). The p-value for an RMFC contusion identifying an occult meniscal tear was found to be statistically significant (between the study group of MRI occult meniscal tears and the control group with meniscal tears visible on MRI) for males and for sexes combined being 0.0003 and 0.01, respectively. The p-value for females was not statistically significant being p-value = 1.0. The p-value of 0.0003 for males indicates a statistically significant difference between the study group (occult meniscal tears) and the control group (tears visible on MRI) in males having an ACL rupture and a concomitant RMFC bone contusion with the RMFC bone contusion being significantly more likely to be present in the patients with an MRI occult meniscal tear.

## DISCUSSION

### Key Results

This study demonstrated a significant association between MRI occult meniscal tears and a bone contusion of the rim of the medial femoral condyle in males with an ACL rupture, consistent with our hypothesis (p-value = 0.0003). There was a statistically significant difference found within the occult tear group based on the sex of the patient. Males with a concomitant ACL rupture were significantly more likely than females to have an occult meniscal tear when an RMFC bone contusion was present,

**Table 2. Meniscal Tear Details in Knees with an Anterior Cruciate Ligament Tear after Radiologist Rereview**

Location of tear	Total menisci	Intact menisci	Torn menisci	Occult torn menisci after rereview of MRI	MRI highest possible sensitivity for meniscal tear if no human error	Total discrete tears	Occult discrete tears after rereview of MRI	MRI highest possible sensitivity for discrete meniscal tear if no human error
Lateral meniscus	790	455	335	20	93.9	355	20	94.3
Medial meniscus	790	404	386	2	99.5	401	2	99.5
Total	1580	859	721	22	96.9	856	22	97.4

**Table 3 - Occult Meniscal Tear Information per the Operative Report**

Size	Type	Location
Small	Radial	Lateral meniscus anterior horn-body junction
Very small	Radial	Lateral meniscus inner third
18 mm	Undersurface partial peripheral long.	Lateral meniscus from the posterior horn to the area of the popliteal hiatus
Small	Partial peripheral long.	Lateral meniscus
Small	Radial	Lateral meniscus
N/A	Partial undersurface peripheral long.	Lateral posterior horn
N/A	Radial	Lateral meniscus red/white zone at the mid body
Small	Frayed partial radial	Lateral meniscus posterior horn near root
Small	Frayed partial radial	Lateral meniscus near root insertion
Small	Radial	Lateral meniscus inner third of meniscal body
5 mm	Partial upper surface peripheral long.	Lateral meniscus superior surface of posterior horn
N/A	Peripheral partial long.	Lateral meniscus posterior horn
Small	Long.	Lateral meniscus mid substance of posterior horn adjacent to root
1 cm	Long.	Lateral meniscus at the edge of the red/white zone
Small, 2 mm	Central long, partial thickness tear	Lateral meniscus posterior horn near root insertion
Minor	Radial	Lateral meniscus
N/A	Complete radial	Lateral meniscal body/ anterior horn junction
Small	Oblique flap tear	Lateral meniscal root insertion
Small	Radial	Lateral meniscal root
N/A	Partial long	Lateral meniscus posterior horn
N/A	Long.	Medial meniscus
N/A	N/A	Medial meniscus

N/A = not available; Long. = Longitudinal

**Table 4. Occult/Study Tear Group and Control Group**

	Occult tear group	Control group
Number of RMFC contusions	10	20
Total number of patients	22	110
Percentage with RMFC contusions	45.5%	18.2%
Males in group with RMFC contusion, Females in group with RMFC contusion	8, 2	14, 6
Males in group without RMFC contusion, Females in group without RMFC contusion	2, 10	57
Total males in group, Total females in group	10 (45.5%), 12 (54.6%)	71 (64.6%), 39 (35.5%)
Mean age at time of MRI, standard deviation (years)	25.86 ± 11.55	31.77 ± 12.85
Maximum age (years)	59	69
Minimum age (years)	13	13

most commonly of the lateral meniscus. This indicates that an RMFC contusion may be used as a predictor of an MRI occult meniscal tear when an ACL tear is present in males (sensitivity = 80.0%). Our data also suggests that the RMFC bone contusion is not a reliable predictor of an occult meniscal tear for female patients (p-value = 1.0 and sensitivity = 16.7%).

Previous studies have not compared differences in patient sex for RMFC bone contusions in the presence of occult meniscal tears. We hypothesize that the difference in sex may be related to the sex difference in coronal slope of the tibial plateau.<sup>9</sup> In males there is a greater coronal slope with the peripheral aspect of the medial tibial plateau (in the coronal plane) being higher or more proximal than the peripheral aspect of the lateral tibial plateau. With this being the case, one could theorize that it may take less energy for bone impaction of the RMFC bone contusion to occur in males than in females. In females, given the wider space or gap between the RMFC bone contusion and medial tibial plateau, much more energy may be needed to cause the RMFC contusions. With higher

**Table 5. Values for RMFC Identifying an Occult Meniscal Tear**

	Total	Male	Female
Sensitivity	45.5% (10/22)	80.0% (8/10)	16.7% (2/12)
P-value (generated from Fisher's Exact Test)	0.01	0.0003	1.0



energy one would expect fewer MRI occult meniscal tears. It has been theorized that MRI occult meniscal tears are more likely to occur in lower energy situations since MRI occult meniscal tears tend to be smaller.<sup>2</sup>

### Generalizability/Comparison

Our overall results of meniscal sensitivity and specificity for the 790 patients with an ACL tear by surgery prior to separating out a control group and a study group were similar to previously reported values in a systematic review of knee MRI evaluation for meniscal tears. Our lateral meniscal sensitivity and specificity of 80.3% (with a 95% CI of 75.6%-84.4%) and 94.8% (with a 95% CI of 92.3% - 96.6%), respectively, were also similar to previously reported values.<sup>11,12</sup> Our medial meniscal sensitivity and specificity of 96.6% (with a 95% CI of 94.3% - 98.2%) and specificity of 96.3% (94.0% - 97.9%), respectively, were mildly higher than previously reported values by Oei of 93.3% and 88.4% for sensitivity and specificity<sup>12</sup>; however, they are similar (within a 95% confidence interval) to previously reported values by De Smet.<sup>11</sup>

However, in the studies that examined knee MRI sensitivity for meniscal tears only in patients with an associated ACL rupture, our sensitivity for detecting lateral meniscal tears is higher at 80% in the lateral meniscus compared to 69% and 59% in prior studies.<sup>1,2</sup> Our percentage of occult meniscal tears in the setting of an ACL rupture is lower at 2.7% (22/790) than in a prior study that reported a percentage of 7.3% (9/122) that used methodology similar to our study.<sup>2</sup> It is felt that the lower percentage of occult meniscal tears and higher sensitivity are likely secondary to improvements in hardware, software, and increased awareness of potential errors in underdiagnosing lateral meniscal tears that have been published in the literature over the past one to two decades.<sup>1,2,3,11</sup>

A prior article has reported that MRI occult meniscal tears were much more common in the lateral meniscus in the ACL deficient knee. We found that almost all occult meniscal tears (20 out of 22) were tears of the lateral meniscus, which is consistent with the prior literature.<sup>2</sup>

In a prior study that primarily focused on MRI evaluation of posterior horn lateral meniscus tears in patients with a concomitant ACL tear, six occult tears were discovered in the posterior horn of the lateral meniscus, all of which were a "partial-thickness or split-type tear."<sup>2</sup> In our study, there were 9 occult tears in the posterior horn of the lateral meniscus of which 7 were partial-thickness or split-type tears, 2 were radial tears, and one was a longitudinal peripheral tear. This again indicates that the most common type of occult tear occurring in the posterior horn of the lateral meniscus in patients with a concomitant ACL rupture is a partial-thickness/split-type

tear. However, unlike the prior study,<sup>2</sup> our findings show that not all occult meniscal tears are partial-thickness or split-type tears, but can also include radial tears and longitudinal peripheral tears (full-thickness).

### Study Limitations

This was a retrospective study, which by nature would be associated with a test interpretation bias (also known as incorporation bias), which would be expected to possibly cause the sensitivity and specificity in our study to be higher than the true sensitivity and specificity in the population studied.<sup>13</sup>

Our study was also exposed to selection bias because only patients who had suspected knee derangement were evaluated with an MRI. Therefore, the information and results from this study should only be applied to patients that have an ACL tear that was clinically suspected prior to the MRI. However, there was the avoidance of verification bias between the control and the study groups, because all patients in the control and the study groups were evaluated diagnostically with surgery and knee MRI.

Even though this study has the largest documented number of reported MRI occult meniscal tears that describes both medial and lateral MRI occult meniscal tears, it is still limited by the small number of MRI occult meniscal tears. This can affect generalizability; however, the types of meniscal tears in this study are consistent with a prior article.<sup>3</sup> Future studies would be helpful in documenting and confirming types of MRI occult meniscal tears.

Last, the radiologists were asked to give a "yes or no" answer to indicate the presence of the RMFC contusion. The substantial inter-observer agreement (based on calculated kappa values) between the three radiologists identifying the RMFC contusion supports reliability among radiologists in identifying the presence of an RMFC contusion on MRI. Even though there was excellent agreement between radiologists supported by high calculated kappa values, we observed that most of the disagreement arose from cases where the presence of the RMFC contusion was not prominent and/or not intense on the MRI images. A weighted kappa may have been higher than the kappa if we had given the radiologists the choice of choosing yes, no, or possible for the presence of a RMFC bone contusion.

### Interpretation

This study demonstrated a high association of the RMFC bone contusion with an occult meniscal tear in males with a concomitant ACL tear. This study also demonstrated significant agreement between radiologists in identifying an RMFC bone contusion. Given these two findings, the RMFC bone contusion can be used as a predictor for the likelihood of an occult lateral

meniscal tear being present in males with a concomitant ACL tear. This bone contusions finding can aid the surgeon by indicating the increased likelihood of an occult tear involving the posterior horn of the lateral meniscus in the appropriate clinical setting of a male with an RMFC bone contusion, normal appearing lateral meniscus on MRI, and an ACL rupture.

The results showed that MRI occult meniscal tears in the ACL deficient knee are not confined to partial thickness tears, as has been previously reported,<sup>2</sup> but include full-thickness radial tears and full-thickness longitudinal tears. In addition, it is important for physicians that interpret knee MRI studies to realize that if a meniscal tear is found at arthroscopy that was not visible on MRI in males with an ACL tear and RMFC, it is not necessarily an error of the interpreting physician (be it an orthopedic surgeon, radiologist, or other physician), but is an intrinsic limitation of MRI to detect certain types of meniscal tears in this group of patients.

#### **Implications for Patient Care**

1. This study demonstrated a bone contusion that has a high association with occult meniscal tears in males with an ACL rupture. This information will alert the orthopedic surgeon to the increased likelihood of an occult meniscal tear in the appropriate clinical setting.
2. The majority of occult meniscal tears were small peripheral vertical tears and small radial tears of the lateral meniscus. This information will alert the orthopedic surgeon to the most common types of occult meniscal tears when there is a high suspicion for an occult tear because of the presence of a bone contusion involving the rim of the medial femoral condyle in males with an ACL rupture.
3. This study demonstrated that the bone contusion of the rim of the medial femoral condyle is reliably seen on MRI.

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# RISK FACTORS FOR OPIOID USE AFTER PATELLOFEMORAL STABILIZATION SURGERY: A POPULATION-BASED STUDY OF 1,316 CASES

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## ABSTRACT

**Background:** Orthopaedic surgeons remain the third-highest group of opioid prescribers among physicians in the United States, accounting for 8% of all opioid prescriptions. The purpose of this study was to identify risk factors for opioid consumption and opioid prescription refills after patellofemoral stabilization surgery. We hypothesized that preoperative opioid use and younger age would be independent risk factors for postoperative opioid use.

**Methods:** Patients undergoing primary patellar stabilization surgery between 2007-2017 in the Humana Inc. administrative claims database were identified using Current Procedural Terminology (CPT) codes for patellofemoral stabilization procedures (CPT-27420, 27422, 27427, 27418). Patients were categorized into opioid naive (N-OU) and those who filled opioid prescriptions within 3 months prior to surgery (OU). Patients in the OU cohort were further categorized into those who filled prescriptions at 1-3 months before surgery (C-OU) and those who filled opioid prescriptions only in the month preceding surgery (A-OU). Descriptive statistics and multivariate analyses were performed to identify risk factors for postoperative opioid use at 3 and 12 months using the open-source R software ([www.r-project.org](http://www.r-project.org)) housed within PearlDiver.

**Results:** A total of 1,316 eligible patients were included. One year postoperatively, there was a greater risk of opioid consumption in the OU cohort (OU vs N-OU: 22.2% vs 4.1%; Relative Risk [RR]: 1.233; 95% CI: 1.172- 1.298; P< 0.0001). C-OU (OR: 5.74; 95% CI: 3.75- 8.9; P< 0.0001),

obesity (OR: 1.76; 95% CI: 1.14- 2.69; P = 0.0099), and preoperative diagnosis of depression or anxiety (OR: 1.83; 95% CI: 1.01- 3.25; P = 0.0435) were independent risk factors for opioid use at 12 months postoperatively. Younger age (age <30) was associated with a lower risk of opioid use at 3 months (OR: 0.3, 95% CI: 0.21- 0.44; P< 0.0001) and 12 months (OR: 0.29; 95% CI: 0.17- 0.46; P< 0.0001) postoperatively.

**Conclusions:** Preoperative opioid utilization significantly increased opioid prescription filling following patellofemoral stabilization surgery. Patient-specific variables including obesity and preoperatively diagnosed depression or anxiety also increased the risk of postoperative opioid utilization. Given the relatively young age and high activity level of patients undergoing patellofemoral stabilization surgery, heightened awareness of patient-specific factors must be considered when selecting appropriate pain management regimens postoperatively.

**Level of Evidence:** III

**Keywords:** knee, patellofemoral, opioid, medial patellofemoral ligament reconstruction, MPFL, tibial tubercle osteotomy

## INTRODUCTION

Orthopaedic surgeons are the third-highest group of opioid prescribers among all physicians in the United States, accounting for almost 8% of all opioid prescriptions.<sup>1</sup> Recent studies in the orthopaedic literature have assessed trends and risk factors for opioid use after surgical procedures.<sup>2,4</sup> However, there is a paucity of literature guiding appropriate opioid use after knee procedures and no clinical consensus currently exists regarding the appropriate dosing of opioids postoperatively.<sup>5,6</sup> In light of the recent opioid epidemic, identification of risk factors for prolonged opioid use after knee procedures may benefit patients and providers.

Patients with patellofemoral instability are frequently active, young patients with specific optimal postoperative pain regimens that remain poorly delineated.<sup>7</sup> Previous literature has indicated that adolescents and adults are commonly overprescribed opioid medications following knee procedures, typically requiring 1/3 of the medications

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that they were prescribed.<sup>8</sup> Kim et al. demonstrated that patients undergoing upper-extremity musculoskeletal procedures used only 34% of the opioid medications they were prescribed.<sup>9</sup> With a large proportion of prescribed opioids available, the potential for abuse or illicit diversion of these medications may substantially contribute to opioid-related abuse.<sup>10-15</sup> It is therefore imperative to identify risk factors for increased postoperative opioid use in patients undergoing surgery for patellofemoral stabilization. Additional patient-specific factors such as obesity may further portend increased opioid usage postoperatively for sports medicine patients undergoing operative interventions of the knee. Especially, there is a paucity of previous studies examining the prevalence of psychiatric comorbidities and their influence on postoperative pain regimens for patients undergoing sports medicine procedures.

The purpose of this retrospective study was to identify risk factors for opioid consumption and opioid prescription refills after patellofemoral stabilization surgery using a large national database. We hypothesized that preoperative opioid usage and younger age would independently increase risk for postoperative opioid use.

## METHODS

### Dataset

A retrospective investigation of the Humana Inc. administrative claims database was performed using the PearlDiver research tool (Fort Wayne, IN, USA). The Humana Inc. administrative claims database houses de-identified data for over 20 million patients, including privately insured and Medicare patients. The Humana Inc. database allows for longitudinal tracking of patients based on unique identifiers. Additional advantages of this database include a large number of patients and the ability to assess multiple demographic and operative factors concomitantly. Patient demographics, medical comorbidities, postoperative complications, and prescription medication can be determined using International Classification of Diseases Ninth and Tenth Revisions (ICD-9 and ICD-10), Current Procedural Codes (CPT), and National Drug Codes (NDC). Because the information in the database is de-identified, this study was granted exemption from the local institutional review board.

### Patient Selection

A retrospective investigation of patients undergoing primary patellar stabilization surgery between 2007 and 2017 in the Humana database (HOrtho) was conducted using CPT codes (CPT-27418, 27420, 27422, and 27427). Only patients with diagnostic codes for patellar instability at the time of surgery were included (Appendix 1). Inclusion criteria was limited to patients who were active

within the HOrtho dataset for at least 3 months prior to surgery and 12 months following patellar stabilization surgery. Patients were also identified according to procedure type as follows: Tibial Tubercle Osteotomy (CPT-27418), and Medial Patellofemoral Ligament Reconstruction (CPT-27420, 27422, and 27427).

Patient records were subsequently queried for all doses of common oral and transdermal formulations of prescription opioids, except for tramadol. This included hydromorphone, oxycodone, hydrocodone, fentanyl, methadone, and morphine. Patients were categorized as opioid naïve (N-OU) if they never filled opioid prescriptions prior to surgery and preoperative opioid use (OU) if they filled opioid prescriptions within 3 months prior to surgery. Patients were further categorized as chronic preoperative opioid user (C-OU) if they filled a prescription opioid medication between 1 and 3 months prior to surgery and acute preoperative opioid use (A-OU) if they only filled prescription opioid medication within 1 month before surgery. This delineation was made to separately analyze patients who may have received opioid medications as a part of their preoperative workup with the medication specifically intended for postoperative use. For the first postoperative year, opioid prescription refills were longitudinally tracked every month after the index patellar stabilization procedure. Prolonged postoperative opioid use was defined as filling at least one opioid prescription after the third postoperative month. Patient demographics and comorbidities were extracted for each cohort using ICD-9 and 10 codes. Demographic and medical comorbidities that were compared between cohorts included age (<30 vs ≥30 years), sex, obesity (body mass index (BMI) ≥30 kg/m<sup>2</sup>), and preoperatively diagnosed depression or anxiety.

### Statistical Analysis

Descriptive statistics were used to report patient demographics, medical comorbidities, and monthly opioid prescription refills for 12 months after surgery. Multivariate analyses were used to identify independent risk factors for prolonged postoperative opioid use with statistical significance set at  $p < 0.05$ . Multivariate analyses were performed at 3 and 12 months after surgery using the open-source R software ([www.r-project.org](http://www.r-project.org)) housed within PearlDiver.

## RESULTS

A total of 1,316 eligible patients were included for analysis. The most common CPT code billed for patellar stabilization surgery was medial patellofemoral ligament reconstruction (79.9%) followed by tibial tubercle osteotomy (20.1%). Of the included patients, 63.5% were female, 66.8% <30 years of age, 16.5% were obese (body



**Table 1. Patient Demographics and Procedures**

Variable	Alln, (%)	N-OU, (%)	OU n, (%)	P- Value
Total	1316 (100)	590 (44.8)	477 (36.2)	
Age <30 (years)	691 (52.5)	394 (66.8)	181 (37.9)	< 0.0001*
Age ≥ 30 years	625 (47.5)	196 (33.2)	296 (62.1)	
Sex				0.1858
Male	480 (36.5)	226 (38.3)	164 (34.4)	
Female	836 (63.5)	364 (61.7)	313 (65.6)	
Obesity	217 (16.5)	38 (6.4)	123 (25.8)	< 0.0001*
History of Psychiatric Co-Morbidity	85 (6.5)	14 (2.4)	50 (10.5)	< 0.0001*
<b>Breakdown by Procedure Type</b>				
Tibial Tubercle Osteotomy (CPT-27418)	265 (20.1)	121 (20.5)	90 (18.9)	0.5035
Medial Patellofemoral Ligament Reconstruction (CPT-27420, 27422, 27427)	1051 (79.9)	469 (79.5)	387 (78.9)	0.5035
<b>Breakdown by Location</b>				
Midwest	398 (30.2)	190 (32.2)	132 (27.7)	0.1090
Northeast	<11	<11	<11	
South	725 (55.1)	307 (52)	278 (58.3)	0.0415*
West	184 (14)	87 (14.8)	64 (13.4)	0.5360

mass index ≥ 30 kg/m<sup>2</sup>), and 6.5% had a preoperative diagnosis of depression or anxiety. Patients were categorized as N-OU (n = 590, 44.83%), OU (477, 36.3%), A-OU (203, 15.4%), and C-OU (274, 20.8%) (Table 1). Patients in the OU cohort were more likely to be older than 30 years (62.1% vs 33.2%, p <0.0001), obese (25.8% vs 6.4%, P <0.0001), and diagnosed with preoperative anxiety or depression (10.5% vs 2.4%, p <0.0001).

In total, 989 (75.2%) patients undergoing patellofemoral stabilization surgery filled opioid medications within 1 month following surgery. In the following months, the use of opioid consumption decreased to 235 (17.9%) at 3 months, 182 (13.8%) at 6 months, 161 (12.2%) at 9 months and 147 (11.2%) at 12 months. The N-OU cohort had a significantly lower rate of opioid prescription refilling (Figure 1), with decreasing rates of opioid filling postoperatively for both the N-OU and OU cohorts within one-year postoperatively (Table 2). At one year after patellar stabilization, there was a significantly greater risk of opioid consumption in the OU cohort (OU vs N-OU: 22.2% vs 4.1%; Relative Risk [RR]: 1.233; 95% CI: 1.172- 1.298; P < 0.0001) (Table 2).

Multivariate logistic regression models were also performed to identify independent risk factors for filling opioid prescriptions at 3 and 12 months after surgery (Table 3). The multivariate model identified both A-OU (Odds Ratio [OR]: 2.67, 95% CI: 1.66- 4.25; P < 0.0001) and

C-OU (OR: 9.02; 95% CI: 6.20- 13.24; P < 0.0001) as independent risk factors for opioid use at 3 months after surgery. Similarly, C-OU (OR: 5.82; 95% CI: 3.80- 9.04; P < 0.0001), obesity (OR: 1.79; 95% CI: 1.16- 2.76; P = 0.0082), and preoperative diagnoses of depression or anxiety (OR: 1.90; 95% CI: 1.04- 3.39; P = 0.0325) were independent risk factors for opioid use at 12 months after surgery. Younger age (age <30) was associated with a significantly lower risk of opioid use at 3 months (OR: 0.29, 95% CI: 0.19- 0.43; P < 0.0001) and 12 months (OR: 0.29; 95% CI: 0.17- 0.48; P < 0.0001) following surgery. Tibial tubercle osteotomy (p= 0.1) and medial patellofemoral ligament reconstruction (p=0.52) were not significant risk factors for opioid use at 3 and 12 months after surgery (Table 3).

**DISCUSSION**

In this retrospective analysis, independent risk factors for increased opioid prescription filling following patellofemoral stabilization surgery included preoperative opioid use, preoperative diagnosis of depression or anxiety, and obesity. Younger age (<30 years) was independently associated with lower rates of opioid prescription filling after surgery. There is a paucity of information regarding optimal pain management regimens postoperatively following patellofemoral stabilization surgery and due consideration to patient-specific risk factors for postoperative usage merits discussion.

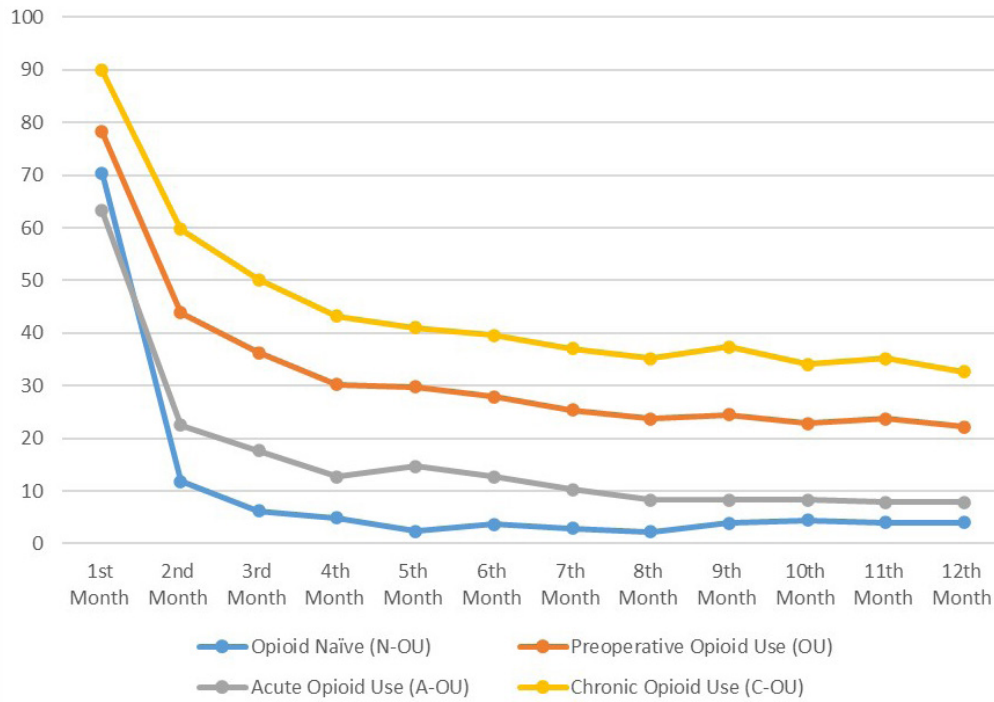


Figure 1. Percentage of Patients Filling Opioid Prescriptions

Table 2. Opioid Prescriptions Filled Postoperatively

Postoperative Month	OU (n = 477)		ON (n = 590)		RR	95% Confidence Interval		P
	Opioid Prescriptions (n)	%	Opioid Prescriptions (n)	%		Lower	Upper	
1	373	78.20	415	70.34	1.36	1.102	1.679	0.004*
2	209	43.82	70	11.86	1.569	1.441	1.797	< 0.0001*
3	173	36.27	37	6.27	1.471	1.37	1.579	< 0.0001*
4	144	30.19	29	4.92	1.362	1.28	1.449	< 0.0001*
5	142	29.77	14	2.37	1.39	1.309	1.476	< 0.0001*
6	133	27.88	22	3.73	1.335	1.26	1.415	< 0.0001*
7	121	25.37	17	2.88	1.301	1.233	1.374	< 0.0001*
8	113	23.69	13	2.20	1.282	1.217	1.349	< 0.0001*
9	117	24.53	23	3.90	1.273	1.207	1.344	< 0.0001*
10	109	22.85	26	4.41	1.239	1.176	1.305	< 0.0001*
11	113	23.69	24	4.07	1.257	1.193	1.325	< 0.0001*
12	106	22.22	24	4.07	1.233	1.172	1.298	< 0.0001*

\*Significant Finding (P < 0.05)

**Table 3: Multivariate Analysis at 3 and 12 Months Postoperative**

Risk Factors	3 Months				12 Months			
	OR	95% Confidence Interval		P	OR	95% Confidence Interval		P
		Lower	Upper			Lower	Upper	
Opioid Use Only 1 Month Before Surgery (A-OU)	2.67	1.66	4.25	< 0.0001*	1.43	0.74	2.64	0.2660
Opioid Use from 1 -3 Months Before Surgery (C-OU)	9.02	6.20	13.24	< 0.0001*	5.82	3.80	9.04	< 0.0001*
Age <30	0.30	0.20	0.44	< 0.0001*	0.29	0.18	0.48	< 0.0001*
Sex, Male	0.88	0.61	1.26	0.4839	1.16	0.77	1.75	0.4677
Psychiatric Diagnosis	1.30	0.74	2.26	0.3565	1.90	1.04	3.39	0.0325*
Obese	1.42	0.95	2.10	0.0821	1.79	1.16	2.76	0.0082*
<b>Breakdown by Procedure Type</b>								
Tibial Tubercle Osteotomy (CPT-27418)	1.01	0.41	2.46	0.9800	2.28	0.86	6.17	0.0968
Medial Patellofemoral Ligament Reconstruction (CPT-27420, 27422, 27427)	1.26	0.71	2.35	0.4479	1.27	0.63	2.80	0.5219

\*denotes significant finding (P < 0.05); OR- Odds Ratio

Preoperative opioid use has been demonstrated to increase an individual’s risk of subsequent opioid use following surgery.<sup>16-20</sup> The literature has also demonstrated increased utilization of opioids postoperatively following orthopaedic procedures for patients with a history of opioid use preoperatively.<sup>21-24</sup> Wojahn et al. prospectively assessed 221 patients for risk factors for increased opioid use after orthopaedic knee procedures and identified preoperative opioid use as a risk factor for increased postoperative opioid utilization.<sup>25</sup> Results from the present study indicate that following patellofemoral stabilization surgery, preoperative opioid analgesic users had a longer duration of opioid use postoperatively. At one-year after patellofemoral stabilization, there was a significantly greater risk for opioid refills in the OU as compared to N-OU cohort. Therefore, accurate identification of patient’s exposure to opioids preoperatively is important to identify patients at risk for prolonged prescription opioid use postoperatively. Patients undergoing patellofemoral stabilization surgery are typically young, active individuals.<sup>26,27</sup> Identifying patients at-risk for opioid misuse is particularly important for mitigating opioid abuse and illicit refill of medications postoperatively in these populations.<sup>7,28</sup> In the present analysis, procedure type for the treatment of patellofemoral instability was not an independent predictor of increased postoperative opioid use. The relatively young age of the population may have also influenced the postoperative recovery of these patients and may have mitigated increases in post-

operative opioid use when additional procedures such as medial patellofemoral ligament (MPFL) reconstruction or tibial tubercle osteotomy were additionally performed. A recent retrospective analysis of opioid usage following patellofemoral stabilization surgery at a single academic center demonstrated similar findings to the present work, suggesting that preoperative usage served as a risk factor for postoperative opioid use for patients undergoing patellofemoral stabilization procedures, including MPFL reconstruction or Fulkerson osteotomy procedures.<sup>29</sup>

Previous literature has reported that a history of a psychiatric diagnosis increased the risk of elevated opioid utilization postoperatively.<sup>30,31</sup> Our results indicate that a psychiatric diagnosis of depression or anxiety preoperatively independently served as a risk factor for increased opioid utilization and prescription refills following patellofemoral stabilization surgery. Adequate characterization of preoperative psychiatric comorbidities is therefore crucial to identify patients at-risk for elevated postoperative opioid utilization and prescription refill. Recent investigations from our institution have demonstrated high rates of preoperative psychiatric comorbidities in patients undergoing patellofemoral stabilization procedures, with greater than 20% of patients diagnosed with a preoperative psychiatric comorbidity.<sup>32</sup> Given the findings presented here that preoperative diagnoses of depression and anxiety may influence postoperative opioid utilization rates, improved characterization of preoperative psychiatric comorbidities may be warranted for sports medicine

patients prior to operative intervention. Recent investigations have begun to explore the influence of psychiatric comorbidities on outcomes of interest to orthopaedic patient populations, but the literature is scarce regarding the significance of these medical comorbidities for patients undergoing patellofemoral stabilization procedures and postoperative opioid utilization rates. Khazi et al. most recently demonstrated that preoperative diagnoses of depression or anxiety independently predict increased opioid prescription refilling postoperatively for patients undergoing isolated meniscectomy procedures.<sup>33</sup> Desai et al. demonstrated that psychosocial variables preoperatively may influence and result in worse postoperative outcomes following patellofemoral arthroplasty procedures, citing decreased patients reported outcome measures [PROs] postoperatively.<sup>34</sup> Furthermore, a recent investigation assessing improvements following double-bundle MPFL reconstruction<sup>35</sup> suggested that preoperative depression and anxiety scores preoperatively may not significantly improve following surgical intervention. Likewise, this study reported BMI > 30 kg/m<sup>2</sup> as associated with worse patient-reported outcomes following surgical intervention for patellofemoral instability.<sup>35</sup> Our results also suggest that obesity independently predicted increased utilization and refill of opioid medications postoperatively. Urman et al. identified obesity as a risk factor for opioid based analgesia in a large scale database study in the U.S.<sup>36</sup> Previous orthopaedic literature has suggested that obesity predicted increased opioid utilization postoperatively.<sup>37</sup> Patients with increased opioid utilization postoperatively in these studies were also characterized by lower socioeconomic status and multiple comorbidities including obesity. Therefore, due consideration to social determinants of health may be warranted when identifying patients at higher risk for increased postoperative opioid use.

In the present study, younger age (<30 years) was demonstrated to independently predict decreased opioid refill rates postoperatively. This finding may be surprising given our initial hypothesis that younger age may be associated with increase opioid usage postoperatively and findings by Anthony et al.<sup>17</sup> suggesting that age < 25 years increased risks for postoperative opioid filling following ACL [Anterior Cruciate Ligament] reconstruction. The literature remains inconclusive regarding whether younger age is a risk factor for opioid refilling following orthopaedic knee procedures for sports medicine populations and may need to be evaluated regarding the specific procedure and population in question. A recent investigation of patients undergoing isolated meniscectomy demonstrated that age < 40 years was associated with decreased risk of postoperative opioid utilization postoperatively.<sup>32</sup> We postulate that patient-specific risk factors including preoperative diagnoses of depression

or anxiety, obesity, and age > 30 may confer an enhanced risk for postoperative opioid utilization and that the presence of more than one of these risk factors may increase the risk for postoperative opioid usage most especially. Younger age < 30 years by itself may not pose additional risk for increased postoperative opioid utilization due to the relatively young, active patient populations undergoing patellofemoral stabilization surgery, who may not require high amounts of opioid medications postoperatively due to their higher preoperative functional statuses. Encouragingly, multi-modal pain management strategies incorporating non-opioid pain medications following common sports medicine orthopaedic procedures<sup>38,39</sup> may offer new avenues for reduced opioid usage postoperatively for patients undergoing patellofemoral procedures, warranting further attention to decrease opioid utilization postoperatively for patients undergoing patellofemoral stabilization procedures.

The limitations of this study include the use of de-identified data from an insurance claims database and reliance on accurate coding. The dataset only includes a subset of the United States population and may not be representative of all patients. Data about each individual patient that may influence treatment decisions, such as level of athletic performance, pre-surgical treatment, or surgical indications, are not available. The database predominately contains privately insured patients who may undergo patellofemoral stabilization surgery at a greater rate than those with public forms of insurance. Inclusion criteria was limited to patients who were active within the HOrtho dataset for at least 3 months prior and 12 months following patellar stabilizing surgery and may have excluded some patients from the analysis due to loss of active insurance coverage or missing postoperative follow-up. Patients were characterized as opioid analgesic users if they had filled an opioid prescription within 3 months preceding their patellofemoral stabilization procedure. Opioid utilization was assessed through prescription refills under the patient's identifying information submitted through the Humana or Medicare insurance databases. Patients may also have taken opioid medication that they were not prescribed or filled prescriptions for opioids without utilizing these medications. This analysis did not assess risk factors for opioid utilization beyond 12 months postoperative due to the potential for additional confounding surgeries. Patients may also have undergone additional procedures during the 12 months following patellofemoral stabilization surgery. Additional confounders were not adjusted for in this analysis and may have also contributed to postoperative opioid use and prescription refill rates.



## CONCLUSION

Preoperative opioid utilization significantly increased opioid prescription filling following patellofemoral stabilization surgery. Patient-specific variables including obesity and preoperatively diagnosed depression or anxiety also increased the risk of postoperative opioid utilization. Given the relatively young age and high activity level of patients undergoing patellofemoral stabilization surgery, heightened awareness of patient-specific factors must be considered when selecting appropriate pain management regimens postoperatively.

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**Appendix 1: Current Procedural Terminology (CPT) and ICD9/10 Codes**

<b>Code</b>	<b>Definition</b>
<b>Procedure Codes</b>	
CPT 27418	Tibial Tubercle Osteotomy
CPT 27420	Reconstruction of Dislocating Patella
CPT 27422	Reconstruction of Dislocating Patella with Extensor Realignment
CPT 27477	Ligamentous Reconstruction, knee extra-articular
<b>Diagnostic Codes for Patellar Instability</b>	
ICD-9-71826	Pathological Dislocation of Joint, Lower Leg
ICD-9-71836	Recurrent Dislocation of Joint, Lower Leg
ICD-9-71886	Other joint derangement, not elsewhere classified, lower leg
ICD-9-83630	Dislocation of patella, closed
ICD-10-M2200	Recurrent dislocation of patella, unspecified knee
ICD-10-M2212	Recurrent subluxation of patella, left knee
ICD-10-M222X1	Patellofemoral disorders, right knee
ICD-10-M222X2	Patellofemoral disorders, left knee
ICD-10-M222X9	Patellofemoral disorders, unspecified knee
ICD-10-M223X1	Other derangements of patella, right knee
ICD-10-M223X2	Other derangements of patella, left knee
ICD-10-M223X9	Other derangements of patella

# COMBINED SURGICAL APPROACH TO YOUNG ADULTS WITH HIP DYSPLASIA AND CONCOMITANT INTRA-ARTICULAR PATHOLOGY USING INTRA-ABDOMINAL MONITORING

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## ABSTRACT

**Background:** Combined hip arthroscopy and periacetabular osteotomy (PAO) allows for treatment of intra-articular hip pathology with simultaneous correction of acetabular version and femoral head coverage in patients with symptomatic hip dysplasia. Currently, scant data is available to surgeons regarding optimal technique, sequence of repair, perioperative management, and the use of intra-abdominal monitoring in patients undergoing these combined procedures. The purpose of this study is to describe a two-surgeon, muscle-sparing, approach for sequential hip arthroscopy and PAO for the treatment of adults with acetabular dysplasia and concomitant intra-articular hip pathology.

**Methods:** In this article, we present the indications for combined hip arthroscopy and PAO, in addition to patient set-up and positioning. A detailed discussion of hip arthroscopy and a muscle sparing PAO techniques are then presented, with overview of a novel intra-abdominal pressure monitoring technique and post-operative rehabilitation protocol.

**Results:** Through technical refinement and experience, our indications and protocol for the treatment of patients with symptomatic acetabular dysplasia with concomitant intra-articular hip pathology involves a refined and reproducible, two surgeon procedure utilizing hip arthroscopy followed by PAO. The use of intra-abdominal monitoring allows for assessment of intra-peritoneal pressures to monitor for the development of abdominal compartment syndrome secondary to fluid extravasation.

**Conclusion:** The performance of concomitant hip arthroscopy and PAO for concurrent hip dysplasia and intra-articular hip pathology represents an increasingly common approach in hip preservation surgery. The hip arthroscopy and muscle-sparing PAO protocol using intra-abdominal monitoring described here serves to further refine and advance the indications and technical aspects of this challenging procedure.

**Level of Evidence:** V

**Keywords:** femoroacetabular impingement, hip dysplasia, hip arthroscopy, periacetabular osteotomy

## INTRODUCTION

The Bernese periacetabular osteotomy (PAO), originally described by Ganz, is recognized as an effective reconstructive treatment for symptomatic acetabular dysplasia.<sup>1,2</sup> Clinical outcomes following PAO have shown predictable and reliable deformity correction, pain relief, and restoration of hip function with low rates of premature osteoarthritis and need for conversion to total hip arthroplasty.<sup>3,5</sup>

Addressing intra-articular abnormalities within the hip has gained increased interest given the high prevalence of concomitant femoroacetabular impingement (FAI) and associated intra-articular pathology in young, active patients.<sup>6</sup> While hip arthroscopy has been shown to effectively treat FAI and other intra-articular injuries, arthroscopy alone in patients with dysplasia remains controversial.<sup>7,8</sup> Decreased functional scores and accelerated progression of degenerative changes in the hip have been reported in patients with hip dysplasia treated with arthroscopy alone.<sup>8</sup> Conversely, when PAO is performed in isolation, higher rates of secondary surgery, acceleration of arthritic changes, and poor patient-reported functional outcomes have been described due to failure to adequately address concurrent FAI and intra-articular pathologies.<sup>9</sup> <sup>10</sup> Moreover, recent literature suggests that performance of combined hip arthroscopy and PAO yield promising results in patients with hip dysplasia and concomitant FAI.<sup>11-15</sup>

Currently, treatment of hip dysplasia and FAI with associated intra-articular hip pathology during a

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single operative visit has been popularized as a means of decreasing the risks associated with a two-staged procedure, namely a lower risk of anesthetic complications by avoiding a second instance of general anesthetic along with decreased post-operative rehabilitation time.<sup>15</sup> However, there remains little information with regard to optimal surgical technique, sequence of repair, role of osteochondroplasty, intra-operative monitoring for intra-peritoneal fluid extravasation, perioperative management, and number of involved surgeons. We offer an overview of the indications and techniques using a two-surgeon approach for sequential hip arthroscopy and PAO for the treatment of adults with acetabular dysplasia and concomitant FAI with intra-articular pathology.

## METHODS

### Indications

Patients with symptomatic acetabular dysplasia and FAI with labral injury are indicated for combined PAO with hip arthroscopy following failure of conservative treatment. Initial radiographic analysis involves anteroposterior (AP), Dunn lateral, false profile, and Judet views to allow for calculation of lateral center edge angle (LCEA), acetabular index (AI), anterior center edge angle (ACEA), and extrusion index (EI). Patients with a LCEA less than 20°, ACEA less than 18°, AI greater than 9°, and EI greater than 20% are classified as dysplastic [14]. Alpha angle measurements ranging from 42 to 65° are diagnostic of femoral head-neck CAM deformity.<sup>14</sup> Magnetic resonance imaging (MRI) is obtained to evaluate for the presence of chondral and labral pathology, as well as the presence of bony edema within the femoral neck. Computed tomography (CT) is utilized to evaluate for acetabular anteversion or relative retroversion. Patients considered for combined PAO and hip arthroscopy are typically young adults with closed triradiate cartilage, a congruent hip joint, and minimal evidence of secondary osteoarthritis, defined by Tonnis grade of 0-1. Contraindications to surgery include moderate to advanced osteoarthritis (Tonnis grade  $\geq 2$ ), significant hip joint incongruity or preoperative hip motion restriction, and medical comorbidities precluding safe induction of anesthesia (i.e. arrhythmias, severe valvular disease), as well as patients with significant risks for non-union or wound complications (i.e. poorly controlled diabetes, smoking). Relative contraindications include patient age  $> 40$  and obesity (body mass index  $> 40$ ).

### Operating Room Preparation and Anesthesia

Surgery is performed by two fellowship-trained orthopaedic surgeons, one specializing in hip arthroscopy and the other in PAO and open hip preservation. Hip arthroscopy is performed using a traction table and upon

completion, the patient is transferred to a flat-top radiolucent table for the PAO. Intra-operative fluoroscopy is used for both procedures. Although hip arthroscopy is typically performed prior to PAO at our institution, the authors previously utilized a PAO-first technique, which is recommended while the PAO surgeon is within the learning curve for this operation, as surgical dissection can be more technically challenging following arthroscopy due to fluid extravasation. Performance of hip arthroscopy first also allows for identification of intra-articular pathology to the labrum and cartilage which may be beneficial when appropriately treated arthroscopically via repair and/or debridement prior to PAO.<sup>11</sup> In addition, if arthroscopic visualization demonstrates a higher grade of chondral damage within the joint than that appreciated on pre-operative imaging, PAO may be contraindicated, with hip arthroplasty being more appropriate.<sup>11</sup>

An epidural catheter is placed prior to the procedure for peri-operative pain control. General anesthesia with skeletal muscle relaxation is employed. Hypotensive anesthesia with a systolic goal of approximately 90mmHg is preferred to minimize blood loss. Arthroscopy pump pressure is monitored closely to minimize fluid extravasation into surrounding soft tissues, which can complicate surgical dissection during subsequent PAO or result in abdominal compartment syndrome if sequestered in the peritoneum.<sup>16</sup> For this reason, intra-operative bladder pressure monitoring is recommended throughout the case when the arthroscopy is performed second due to the risk of a traumatic rent in the peritoneal fascia during the PAO procedure. Intravenous tranexamic acid and an autologous red blood cell recycling system (CellSaver, Haemonetics, Braintree, MA) are used to minimize peri-operative autologous blood transfusion requirements.

### Hip Arthroscopy Technique

Hip arthroscopy is performed on a traction table and the patient is positioned atop a non-slip friction pad (The Pink Pad, Xodus Medical, Pittsburgh, PA) to allow for post-less distraction. (Fig. 1A) 8 to 10 mm of distraction is preferable. A well-padded perineal post may be alternatively utilized with Trendelenburg positioning of 10-15° shown to decrease perineal pressure when compared to neutral (0°) positioning.<sup>17</sup> The hip will need to be vented to maximize distraction distance and an air arthrogram is performed to visualize the intra-articular space. (Fig. 1B) A standard anterolateral arthroscopy portal is created under fluoroscopic guidance followed by a modified mid-anterior portal created under direct visualization. An interportal capsulotomy is then performed. Care is taken to maintain the intact capsule antero-medially over the psoas tendon. The capsulotomy is placed with 7 to 9 mm of remaining proximal capsule on the acetabular side. The

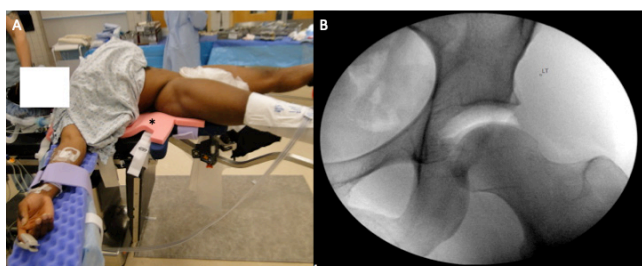


Figure 1. Hip arthroscopy set-up with (A) patient on traction table using non-slip friction pad (\*) to counter traction applied to operative leg, with (B) fluoroscopic image of the operative hip following air arthrogram demonstrating distraction of the hip joint using post-less traction.

proximal capsular flap is preserved for repair at the conclusion of the case. The acetabular rim is exposed using the arthroscopic shaver and radiofrequency device. Rim decortication and sub-spinous decompression, when necessary, are then performed. The labrum is repaired with suture anchors in varying positions based on the extent and characteristics of the tear pattern. Sutures are shuttled in a trans-labral fashion and a base refixation technique is utilized to avoid excessive eversion of the labrum and to enhance the suction seal effect. The anterior superior and posterior superior aspects of the acetabulum are inspected for chondral defects amenable to chondroplasty if unstable or using a marrow stimulation technique if a full thickness defect is noted. Intra-articular loose bodies are removed when encountered. Traction is then released and the quality of the labral suction seal is visualized.

The peripheral compartment is then addressed, beginning with release of the fascial attachments of the lateral capsule. Retention sutures are then utilized to aid in the distraction of the distal capsular flap. The femoral head-neck junction is inspected for CAM lesions and to visualize and protect the lateral retinacular vessels. A distal anterolateral portal is created under direct visualization and an osteoplasty is performed under fluoroscopic guidance from the medial to lateral synovial fold proximally and to the extent of the lesion distally. A dynamic examination is performed following osteoplasty to evaluate for residual

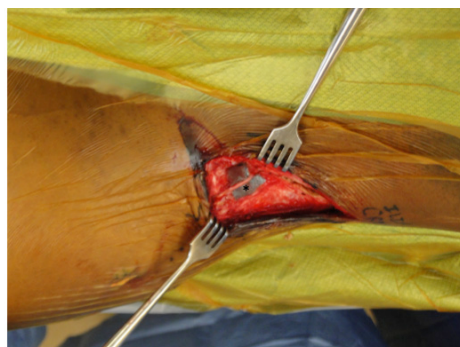


Figure 3. Superficial dissection showing identification of lateral femoral cutaneous nerve (\*).



Figure 2. Operative limb following hip arthroscopy demonstrating curvilinear incision running from the iliac crest proximally and extending distally and medially over anterior superior iliac spine (ASIS), tension fascia lata (TFL) and sartorius (S).

impingement. Capsular plication is then performed in the inter-portal capsulotomy with multiple sutures. The hip is then drained, the arthroscope withdrawn, and portal sites are closed primarily.

### PAO Surgical Technique

The patient is positioned supine on a radiolucent table. A modified limited iliofemoral approach is used for exposure. An 11 cm curvilinear incision is made beginning proximally along the iliac crest and extending distally and medially over the bulk of the tensor fascia lata just caudal to the inguinal crease (Fig. 2). This “bikini” incision within the flexor crease of the hip offers improved post-operative cosmesis. Superficial dissection involves the release of the external oblique aponeurosis from the iliac crest. The iliac fossa is entered bluntly. Distally, the Heuter interval is opened over the mid-portion of the tensor fascia lata. The fascial incision is lateral to the traditional Smith-Peterson approach to protect the lateral femoral cutaneous nerve (LFCN) (Fig. 3). A sartorius tenotomy is then performed and is preferred over an anterior superior iliac spine (ASIS) osteotomy due to ease of repair and to minimize screw traffic in the ilium (Fig. 4). The superior pubic ramus is exposed subperiosteally with the hip in flexion to relax the iliopsoas. Dissection is carried far medial to the iliopectineal eminence and the iliopectineal fascia is



Figure 4. Tenotomy of the sartorius (\*) using electrocautery.

released off the inner portion of the quadrilateral plate to increase mobility of the osteotomy fragment. The origin of the rectus femoris from the anterior inferior iliac spine (AIIS) is preserved during dissection.

The superior edge of the obturator foramen is identified next to ensure extra-articular position of the pubic osteotomy. A custom, sharp pointed modified Hohmann retractor (Innomed, Inc, Savannah, GA) is used to expose the superior surface of the superior pubic ramus. A three-fourths inch straight osteotome is then used, oriented obliquely, to perform the pubic osteotomy. While digital palpation is generally utilized to ensure appropriate medial dissection into the obturator foramen and osteotome position, if the medial extent of our position on the ramus is unclear, fluoroscopy using an obturator oblique view can be used to confirm appropriate osteotome placement. Care should be taken to avoid the obturator neurovascular bundle with the osteotome.

Once the pubic osteotomy is complete, fluoroscopy is used to obtain baseline radiographic views of the pelvis as reference for subsequent correction. The sagittal plane orientation of the pelvis is matched to the pre-operative weight-bearing AP pelvis radiograph using the profile of the obturator foramen to accommodate for lumbar lordosis and pelvic tilt. The interval between the medial femoral neck and iliopsoas tendon is then developed by blunt dissection medial to the origin of the rectus femoris tracking inferiorly to the medial femoral neck. Curved dissection scissors are used to dissect through the thick connective tissue layer leading to the posterior aspect of the femoral neck. With the hip in extension, a small, offset, tined osteotome is placed through this interval. The osteotome is then used to dissect the periosteal and capsular tissue from the anterior aspect of the ischium so that it can rest in the infra-cotyloid groove. Alternating between AP and iliac oblique fluoroscopic images, the ischial osteotomy is then performed in the lateral, central, and medial portions of the ischium.

Next, position for the iliac osteotomy is confirmed with a radiopaque guidewire. Its orientation should parallel the superior portion of the joint surface and be located between the ASIS and AIIS. An oscillating saw is used to make this incomplete osteotomy. Care should be taken to avoid extending this osteotomy beyond the brim of the pelvis to preserve the integrity of the pelvic ring. This osteotomy should connect to the ischial osteotomy within the substance of the posterior column on an iliac oblique view.

The final osteotomy is performed within the posterior column connecting the iliac and ischial osteotomies using tined osteotomes along the medial and lateral portions of the posterior column using an iliac oblique view on fluoroscopy, with care to avoid drifting towards and damaging

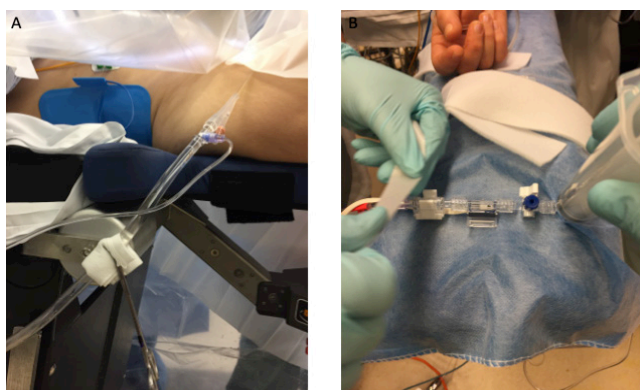
the acetabulum. A threaded 5mm Schantz pin is then placed in the supra-acetabular bone to manipulate the osteotomy fragment. If the fragment is not fully mobile, the superior, lateral, and posterior corners of the fragment should be evaluated to confirm they are adequately released. A cannulated version of the Lane bone holding clamp (Innomed, Inc, Savannah, GA) is then used to firmly grasp and manipulate the osteotomy fragment. After unlocking the pubic ramus, the fragment should be free for reorientation based on patient specific deformities. After initial correction is performed, temporary fixation is achieved using 2.9 mm terminally threaded wires. The acetabular index is used to assess slope of the sourcil and the EI is used to assess anteversion. Final fixation is performed with four 4.5 mm titanium solid screws. Supplementary screws can be placed in the supra-acetabular corridor from the AIIS into the posterior iliac wing above the greater sciatic notch. Titanium screws are utilized to allow for postoperative MRI if necessary and are generally removed 9 to 12 months following placement.

Prior to deep closure, careful inspection of the under-surface of the proximal portion of the iliopsoas is performed to identify and repair any trans-muscular defects that could lead to intra-abdominal fluid extravasation if arthroscopy is to follow the PAO. The sartorius is then repaired back to the ASIS through a bone tunnel using heavy non-absorbable suture. The fascia of the external oblique and tensor fascia lata are repaired in a watertight fashion. One deep drain is placed to reduce risk of post-operative fluid collection. Dermal and epidermal closure is then performed in layers.

### **Intra-Abdominal Pressure Monitoring**

Intra-abdominal pressure is commonly measured by monitoring urinary bladder pressure in critically ill patients.<sup>18</sup> We utilize a bladder pressure monitoring technique similar to that described for this patient population. A Foley catheter is inserted into the bladder allowing it to empty completely. The urine drainage port is then clamped distal to the balloon port (Fig. 5A). To calibrate the initial bladder volume, 30 mL of normal saline is injected into the bladder. With the tubing remaining clamped, an external pressure transducer, obtained from an arterial line set up, is connected to the balloon port of the catheter and the stopcock is placed in neutral position (Fig. 5B). The line is then calibrated and the scale of the readout on the electronic transducer amplifier display is set from 0-30mmHg. Normal bladder pressures in this setting range from 8-14 mmHg prior to initiating arthroscopy. During arthroscopy, pump pressure is adjusted to maintain a bladder pressure less than 20mmHg, as abdominal compartment syndrome is described with pressures above this threshold.<sup>18</sup> Both deep and superficial





**Figure 5.** Intra-abdominal pressure monitoring set-up using (A) foley catheter inserted into the bladder and clamped following emptying of the bladder, followed by (B) injection of 30 mL of normal saline into the bladder with application of external pressure transducer to calibrate and allow for measure of intra-operative bladder pressure.

drains are placed following PAO and allowed to drain to gravity into a canister during arthroscopy to allow for passive egress of arthroscopy fluid.

### **Post-Operative Rehabilitation**

The epidural catheter is removed post-operative day 1, after which the patient is transitioned to a multimodal oral pain regimen. Patients receive aspirin for deep vein thrombosis prophylaxis 8 hours following removal of the epidural catheter. No hip range of motion precautions, braces, or continuous passive motion machines are utilized post-operatively. Outpatient follow up is scheduled for 2, 6, 12 weeks, 6 months, and 1 year post-operatively. Radiographs of the pelvis are obtained at each visit. Patients are restricted to thirty pounds flat foot weight bearing for 6 weeks post-operatively before transitioning to weight-bearing as tolerated. Physical therapy does not commence until full weight-bearing is initiated. Post-operative weeks 6 to 12 are focused on gait training and hip girdle strengthening; weeks 12 to 16, on low impact and closed-chain activities such as elliptical machine, rowing, with progression to walking, and jogging. After this period, patients may begin sport-specific training and conditioning exercises. Return to sport is anticipated at 6 months post-operatively following radiographic evidence of osteotomy union and appropriate advancement in rehabilitation protocol.

### **DISCUSSION**

The PAO is a widely accepted treatment for symptomatic acetabular dysplasia with continued benefits reported at mid- and long-term follow up.<sup>9,11</sup> Clinical outcomes after PAO have shown improvement in pain relief and hip function when compared with pre-surgical baselines.<sup>11-15,19</sup> Labral, chondral, and CAM lesions are frequently present in patients with hip dysplasia and associated with inferior

outcomes when left untreated.<sup>6,8,19</sup> As a result, treatment of concomitant FAI and intra-articular pathology at the time of pelvic osteotomy has the potential to improve functional outcomes and reduce pain in patients with associated acetabular dysplasia.

Few prior studies have describes surgical techniques and outcomes following hip arthroscopy used in conjunction with PAO.<sup>20,21</sup> Kim et al. reported methodology and outcomes utilizing combined arthroscopy and PAO, describing a transtrochanteric approach in the lateral decubitus position where the hip capsule is exposed through a trochanteric osteotomy.<sup>12</sup> Hip arthroscopy was then performed following capsular exposure under manual traction instead of standard arthroscopic technique. The authors identified labral lesions in 88% of subjects with acetabular dysplasia and found that addressing these intra-articular lesions arthroscopically in addition to osteotomy resulted in improved Harris Hip Scores (HHS) from 72.4 to 94 at a mean 74-month follow up. Our described technique offers a less invasive, combined approach to intra-articular pathology, allowing for superior visualization of chondrolabral pathology using standard arthroscopic technique without the morbidity associated with trochanteric osteotomy, thereby decreasing rehabilitation and time to weight bearing post-operatively.

Multiple studies by Domb et al. have reported significant improvements in HHS following combined hip arthroscopy and PAO in patients with acetabular dysplasia and intra-articular pathology.<sup>6,11,14</sup> In their 2015 study consisting of a cohort of 17 patients, chondrolabral pathology was identified in all patients and labral repair, versus debridement alone, was performed in 71% of patients.<sup>11</sup> The authors described utilization of standard arthroscopic technique to evaluate and treat intra-articular pathology using traction for optimal visualization of the central compartment of the hip. The surgical approach utilized by Domb et al. differs from our described technique by using a standard Ganz technique with ASIS osteotomy and violation of the rectus femoris. This can delay post-operative mobilization and rehabilitation and is therefore avoided in our practice.

Potential complications related to combined procedures include sciatic neurapraxia, resulting in a potential double hit phenomenon during the combined procedure.<sup>11</sup> However, sciatic nerve injury as a direct result of prolonged traction time has not been observed in recent literature.<sup>11-14</sup> A more common neurologic risk following either hip arthroscopy or PAO is injury to the LFCN, which we avoid using our modified surgical approach.<sup>13</sup> The potential for a pudendal nerve injury is avoided by utilizing post-less traction.

The risk of fluid extravasation during hip arthroscopy can increase the complexity of the PAO dissection



due to difficulty identifying tissue planes. Minimizing arthroscopic pump pressure can ameliorate this potential complication, as can efficient arthroscopic technique when performed by an experienced arthroscopy surgeon. The bladder pressure recording technique described above allows for monitoring of intra-peritoneal pressures to avoid potential extravasation-related complications, namely abdominal compartment syndrome.<sup>16</sup>

Concomitant hip arthroscopy and PAO allows for treatment of intra-articular hip pathology with simultaneous correction of acetabular version and femoral head coverage. The muscle-sparing PAO technique described here allows for preservation of the abductor attachments to the lateral iliac crest as well as the rectus femoris attachment, decreasing rates of heterotopic ossification, improving fragment vascularity, and more rapid postoperative recovery. Utilization of an intra-abdominal pressure monitoring system using a foley catheter also provides intra-operative assessment for the potential development of abdominal compartment syndrome from intra-peritoneal fluid extravasation. Overall, the experience with this protocol has been favorable, however as continued refinement and advancement in operative techniques are introduced, the authors aim to continue to improve surgical efficiency and postoperative outcomes.

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