

**Appendix 1** to Primeau CA, Marsh J, Birmingham TB, et al. The importance of costing perspective: an example evaluating the cost-effectiveness of a locking versus nonlocking plate in medial opening wedge high tibial osteotomy? *Can J Surg* 2019.

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## 1 **APPENDIX 1**

### 2 **METHODS**

3 We conducted a retrospective study of patients who had undergone medial opening wedge HTO for varus  
4 malalignment and medial compartment knee OA between July 2005 and June 2015 at the Fowler Kennedy Sport  
5 Medicine Clinic (London, ON). Data were prospectively collected from a study approved by our institution's  
6 research ethics board and all patients had provided informed consent prior to study enrolment to have their data  
7 entered into a research database.

8 One fellowship-trained orthopaedic surgeon (JRG) performed all surgeries using either a locking (Arthrex  
9 ContourLock HTO Plate®) or a non-locking (Arthrex Puddu Plate®) internal fixation plate. Patients at earlier time  
10 points of the study received the non-locking plate. The locking plate was made of titanium, whereas the non-locking  
11 plate was made of stainless steel. Threaded screws for the locking plate provide stability through an equal  
12 distribution of forces through the bone, screws and the plate, whereas the non-locking plate relies on the friction  
13 between the plate and the bone for stability. Additionally, the anatomically curved shape of the locking plate  
14 provides a larger surface for force dispersion and two additional screws for the locking mechanism (six screws total  
15 versus four in non-locking plate).

16 Availability of the locking plate in 2009 resulted in a shift in clinical practice where most patients received the  
17 locking plate. Aside from the locking plate allowing patients to return to full weight-bearing more rapidly however,  
18 the surgical and rehabilitation protocols remained the same for both patient groups. The medial opening wedge  
19 HTO procedure has been previously described [2,5]. Following surgery, the operative limb was placed in a hinged  
20 knee brace. At this time, patients were instructed to feather-touch weight-bear (WB) with the assistance of crutches  
21 for a minimum of two weeks. Once the patient showed clinical and radiographic evidence of osteotomy healing,

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22 they progressed to protective WB. The decision to progress WB was decided by the surgeon using radiographic  
23 evidence of osteotomy healing (i.e. the extent of bone consolidation on radiographs) and the level of pain or  
24 discomfort reported by the patient during ambulation. Patients progressed in WB status until they no longer required  
25 crutches.

26 Patients were also given a standardized progressive rehabilitation protocol to allow them to reestablish full range of  
27 motion, strength and function, in addition to reducing swelling, and avoiding joint contracture and muscle atrophy  
28 from disuse. Patients began this program at three weeks postoperative with lighter exercises and progressed in  
29 exercise difficulty until they exhibited a normal gait pattern at the discretion of the physiotherapist. All patients  
30 followed the same rehabilitation protocol with slight modifications if necessary.

31 All patients were seen in clinic for a follow-up visit with the surgeon at two and six weeks and three, six and 12  
32 months after surgery. Intraoperative or post-operative complications requiring additional surgical intervention (e.g.  
33 deep infection, non-union) were collected.

34

35 **OUTCOME MEASURES.** The Knee injury and Osteoarthritis Outcome Score (KOOS) is a self-administered knee  
36 and OA-specific questionnaire that addresses five domains of health: pain, other symptoms, function during  
37 activities of daily living, function during sport and recreational activities, and quality of life related to the knee. The  
38 tool uses a five-point ordinal scale for each item and generates a standardized mean value score to represent each of  
39 the five domains ranging from 0 (worst outcome) to 100 (best outcome). The KOOS has been shown to exhibit  
40 excellent test-retest reliability in each domain (range 0.75-0.93), face validity, construct validity, and responsiveness  
41 to change for individuals with knee OA [10,11].

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42 All direct costs associated with the HTO procedure were reported using the average procedure cost from the Ontario  
43 Case Costing Initiative [7] in addition to costs associated with any additional surgeries (e.g. revisions, hardware  
44 removals, irrigation and debridement for infection). These costs included operating room costs, equipment used, and  
45 other medical tests performed, as well as the length of stay in the hospital following surgery. Surgeon and  
46 anaesthesiologist billing fees were obtained through the Ontario Ministry of Health Schedule of Benefits [8]. The  
47 costs for the individual plates and their associated fixation screws were obtained from our institution's case costing  
48 department.

49 We also recorded any additional healthcare resource use for 12 months following the HTO surgery by reviewing  
50 patient clinic charts and electronic hospital records. All clinic consultations, follow-up visits, emergency room visits  
51 and hospitalization, diagnostic imaging and laboratory tests performed and additional procedures performed for  
52 postoperative complications requiring further intervention were recorded. Costs were attained from the Ontario Case  
53 Costing Initiative, and billing fees were obtained from the Ontario Ministry of Health Schedule of Benefits [8].

54 We recorded employment time lost, and homemaking or volunteer time lost. The total time was determined in one  
55 of two ways. If patients returned to the clinic for a follow up visit during the study period, they were asked to  
56 indicate their employment status at the time of surgery, and time off work from paid employment (or retirement,  
57 homemaking activities, etc.) as a result of the HTO. If patients did not return to the clinic during the study period,  
58 we reviewed the surgeon dictated clinic follow-up reports up to 12 months following the HTO to identify the  
59 patient's occupation and references of date to return to employment.

60 The 2015 average Canadian wage reported by Statistics Canada was used to value time off employment [12]. We  
61 assigned the current value of minimum wage in Ontario to account for time off for patients who were retired, or who  
62 lost time from home making or volunteering activities.

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63 We estimated the total cost for each individual patient over the study period. All costs were reported in 2016  
64 Canadian dollars.

65

66 STATISTICAL ANALYSIS. We conducted a cost-effectiveness analysis from the healthcare payer and societal  
67 perspectives. The healthcare payer perspective includes the direct costs from healthcare resources consumed  
68 including the HTO surgery, any additional procedures (e.g. revision surgeries), diagnostic testing and inpatient  
69 hospitalizations. The societal perspective includes these same costs along with out-of-pocket patient costs (e.g.  
70 injections) and indirect costs such as time off employment and/or homemaking activities as a result of the surgery.  
71 We included all costs up to 12 months following surgery and used the KOOS total change score from baseline to 12  
72 months postoperative as our effectiveness measure. We calculated the incremental cost-effectiveness ratio (ICER),  
73 which is the ratio between the incremental cost and the incremental effect (change in KOOS).

74 We also estimated cost-effectiveness using the net benefit regression (NBR) framework [3], a statistical tool that  
75 considers both the incremental cost and effect of an intervention in addition to the maximum acceptable amount one  
76 is willing-to-pay (WTP) to achieve one additional unit improvement in effect. In this framework, an intervention is  
77 deemed more cost-effective than the existing treatment if the incremental net benefit (INB) is greater than zero.

78 The use of the net benefit regression framework in our CEA allows to control for baseline variables and to explore  
79 potential interaction terms for a richer understanding of the cost-effectiveness, which can be limited when solely  
80 exploring incremental cost-effectiveness ratios [3].

81 We conducted two individual NBR models to evaluate from both the payer and societal perspectives. The WTP  
82 values used varied between \$0 and \$2,000. We included the following covariates in our models: age, sex, BMI,  
83 comorbidities and baseline mechanical axis angle (MAA).

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84 To characterize the statistical uncertainty, we presented 95% CIs around our estimates of the incremental net benefit  
85 (INB) and with a cost-effectiveness acceptability curve (CEAC) [4]. The CEAC provides a functional  
86 representation of probability that the treatment is cost-effective at various WTP values.

87 We conducted one-way sensitivity analyses on the variables that were considered to have the most uncertainty  
88 because of the assumptions required to calculate the cost: 1) the dollar value for retired or home making time  
89 (ranging from \$0 per hour to \$11.25 per hour); 2) adding seven weeks to the return to full weight-bearing time for  
90 patients where we were unable to collect a return to work time and using this value as their time to return to work, as  
91 seven weeks was the mean time to return to work from return to full weight-bearing in our sample; 3) combining the  
92 adjustments of sensitivity analyses 1 and 2.

93 We used Multiple Imputation methods to impute missing 12 month KOOS total change score data. A pooled score  
94 was generated from 5 individual imputations to provide a best estimate value. Covariates including age, sex, BMI,  
95 comorbidities, baseline MAA and baseline total KOOS were used in the model to increase the accuracy of the  
96 imputed values.

97

## 98 **RESULTS**

99 We screened 502 HTO procedures that were captured in our database. Patients were excluded if they received an  
100 alternative fixation device, underwent a combined procedure (e.g. simultaneous anterior cruciate ligament  
101 reconstruction and HTO) or had a subsequent lower limb surgery within 12 months of surgery. Of the screened  
102 patients, 248 met the eligibility criteria and were included. From this sample, 143 patients underwent a medial  
103 opening wedge HTO using the locking plate, while 105 patients received the non-locking plate.

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104 Baseline demographics and clinical characteristics were similar between groups (Table 1). Patients were typically  
105 male, middle-aged and categorized as overweight from their BMI. Patients were varus aligned as defined by their  
106 MAA and had large correction sizes. No statistically significant differences were observed between groups. We  
107 evaluated severity of OA from semi-flexed posteroanterior radiographs and used the Kellgren and Lawrence (K/L)  
108 grading scale [6]. Patients had moderate to severe OA in the medial compartment of the tibiofemoral joint (over  
109 90% with K/L grades 2 to 4 in both groups). According to the American Society of Anesthesiologists (ASA) score,  
110 most patients were considered to have mild systemic disease.

111 Incidence of post-operative complications requiring further intervention was similar between groups. Three patients  
112 required irrigation and debridement of their incisions for infection in the locking plate group, while there was one  
113 patient required revision surgery for a non-union in the non-locking plate group. A pulmonary embolism was  
114 confirmed with chest radiographs for one patient in the locking plate group and was treated with thrombolytic  
115 medication. A deep vein thrombosis (DVT) was documented through ultrasound for one patient in the locking plate  
116 group and was treated with an anticoagulant. All patients recovered with no long-term effects. No cardiovascular or  
117 neurovascular injuries were reported. A total of 11 patients (8.3%) with the locking plate complained of irritation at  
118 site of osteotomy following the surgery and had the hardware surgically removed within the first 12 months  
119 postoperatively, compared to eight patients (7.6%) in the non-locking plate group.

120 COST AND EFFECT. The mean cost of using the locking plate was significantly greater compared to the non-  
121 locking plate from the healthcare payer perspective (Table 2). From the societal perspective; however, use of the  
122 locking plate saved significantly more money compared to the non-locking plate. The mean between group  
123 difference in effect (KOOS change score) was small and not statistically significant, but favored the locking plate  
124 group.

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125 ICER. The ICER was \$399.41 per one point improvement in the total KOOS change score for the healthcare payer  
126 perspective (Table 2), translating to an additional \$3,994.10 per patient for a clinically important improvement of ten  
127 KOOS points [9] compared to patients who receive a non-locking plate. The ICER was -\$3745.26 for the societal  
128 perspective, indicating a cost saving of \$3,745.26 per additional one point improvement in total KOOS change score  
129 in favor of the locking plate group or \$37,452.60 for a clinically important improvement of ten KOOS points.

130 NET BENEFIT REGRESSION. From the healthcare payer perspective, the INB was negative for WTP values  
131 <\$1,000, indicating that the locking plate is not cost-effective compared to the non-locking plate below this WTP  
132 threshold (Table 3). The locking plate became cost-effective at a  $WTP \geq \$1,000$ . From a societal perspective, the  
133 INB was positive for all WTP values suggesting that the locking plate is cost-effective compared to the non-locking  
134 plate.

135 UNCERTAINTY. From the healthcare payer perspective, the 95% confidence intervals (CI) around our estimate  
136 widen as WTP increases and even at WTP values  $\geq \$1,000$ , the lower bounds of the 95% CIs remain negative (i.e.  
137 there is still a chance that the locking plate is not cost-effective). To visually display the uncertainty, the probability  
138 of cost-effectiveness for the locking plate is displayed on the cost-effectiveness acceptability curve (CEAC) (Figure  
139 1). The CEAC suggests that even at a WTP of \$1,000 for a one-point improvement in total KOOS change score (i.e.  
140 \$10,000 for a clinically meaningful improvement), the probability that the locking plate is cost-effective is 55%  
141 (Figure 1A).

142 From the societal perspective, the lower bounds of the CI remain positive up to a WTP of \$500, but become  
143 negative at values  $> \$500$ . The CEAC suggests that the locking plate is cost-effective with 99% certainty, at a WTP  
144 value of \$0 (Figure 1B). As WTP increases; however, this certainty slowly declines as a result of cost savings with  
145 minimal improvement in effect [1].

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146 SENSITIVITY ANALYSIS. From the societal perspective, our ICER values were not sensitive to 1) the dollar value  
147 for retired or home making time at 0\$ per hour, 2) time to return to work = time to return to weight bearing plus  
148 seven weeks, and 3) adjustments 1) and 2) together (Table 4). Similarly, our results for net benefit regression did not  
149 change in each of the three sensitivity conditions (Table 5). The INB was positive for all WTP values indicating that  
150 the locking plate is cost-effective compared to non-locking plate.

151

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194 **Table 1: Baseline demographics and clinical characteristics (n = 248)\*.**

<b>Demographic/clinical characteristic</b>	<b>Group 1: Locking Plate (n = 143)</b>	<b>Group 2: Non-locking Plate (n = 105)</b>
Sex, no. (%)		
Male	107 (74.8)	79 (75.2)
Age, years	48.9 ± 8.0	46.7 ± 8.8
Height, cm	175.6 ± 8.3	175.7 ± 9.0

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Mass, kg	92.5 ± 15.3	91.0 ± 17.0
Body mass index (BMI), kg/m <sup>2</sup>	30.0 ± 5.0	29.4 ± 4.4
Operative limb left, no. (%)	76 (53.1)	52 (49.5)
Mechanical axis angle, degrees <sup>a</sup>	-8.5 ± 2.8	-8.1 ± 3.4
Mean correction size ± SD (mm)	11.9 ± 2.6	12.3 ± 3.0
Medial Compartment K/L Grade, no. (%) <sup>b</sup>		
1	11 (7.7)	9 (8.6)
2	48 (33.6)	28 (26.7)
3	60 (42.0)	42 (40.0)
4	21 (14.7)	23 (21.9)
Lateral Compartment K/L Grade, no. (%) <sup>b</sup>		
1	25 (17.5)	53 (50.5)
2	82 (57.3)	31 (29.5)
3	31 (21.7)	10 (9.5)
4	0 (0.0)	0 (0.0)
American Society of Anesthesiologists score, no. (%) <sup>c</sup>		
1	47 (32.9)	37 (35.2)
2	82 (57.3)	54 (51.4)
3	14 (9.8)	14 (13.3)

195 \*Values are reported as means with standard deviations unless otherwise specified

196 <sup>a</sup> A negative mechanical axis value indicates varus alignment

197 <sup>b</sup> Kellgren-Lawrence (K/L) grade of osteoarthritis severity

198 <sup>c</sup> American Society of Anesthesiologists physical status classification system: 1 = healthy, normal patient; 2 =  
 199 patient with mild systemic disease; 3 = patient with severe systemic disease

**Table 2: Cost and effect outcomes\*.**

<b>Healthcare payer (n = 248, CL = 143, PUD = 105)</b>							
<b>Plate</b>	<b>Cost<sup>*,a</sup></b>	<b>Δ Cost</b>	<b>CI, p-value</b>	<b>Effect<sup>*,b</sup></b>	<b>Δ Effect</b>	<b>CI, p-value</b>	<b>ICER</b>
Locking	6785.70	+664.20	(236.6, 1064.8),	21.39	+1.66	(-6.2, 2.9), 0.47	+399.41
Non-locking	6121.49		0.001‡	19.73			
<b>Societal (n = 164, CL = 106, PUD = 58)</b>							
<b>Plate</b>	<b>Cost<sup>*,a</sup></b>	<b>Δ Cost</b>	<b>CI, p-value</b>	<b>Effect<sup>*,b</sup></b>	<b>Δ Effect</b>	<b>CI, p-value</b>	<b>ICER</b>
Locking	23894.88	-6228.21	(-10549.7, -1906.7), 0.005†	21.39	+1.66	(-6.2, 2.9), 0.47	-3745.26
Non-locking	30123.09			19.73			

\*Values are reported as means

<sup>a</sup> 2016 Canadian dollars.

<sup>b</sup> Total change Knee injury and Osteoarthritis Outcome Score (KOOS) between baseline and 12 months

† p < 0.05, ‡ p ≤ 0.001

Abbreviations: ICER = Incremental cost-effectiveness ratio, CI = confidence interval

**Table 3: Net benefit regression results.**

WTP*	Healthcare payer**			Societal**		
	Incremental net benefit <sup>a</sup>	95% CI	p-value	Incremental net benefit <sup>a</sup>	95% CI	p-value
0	-707.00 (216.54)	-1133.6 to -280.4	<0.001‡	5232.19 (2127.32)	1029.9 to 9434.5	0.015†
250	-480.04 (643.65)	-1748.1 to 788.0	0.457	5599.82 (2324.64)	1007.8 to 10191.9	0.017†
500	-253.07 (1231.82)	-2679.8 to 2173.7	0.837	5967.46 (2761.42)	512.6 to 11422.3	0.032†
750	-26.10 (1832.00)	-3635.2 to 3583.0	0.989	6335.09 (3345.13)	-272.8 to 12943.0	0.060
1000	200.88 (2435.30)	-4596.8 to 4998.6	0.934	6702.72 (4012.16)	-1222.8 to 14628.3	0.097
1250	427.85 (3039.88)	-5560.9 to 64166	0.888	7070.35 (4727.36)	-2268.0 to 16408.7	0.137
1500	654.82 (3645.11)	-6526.3 to 7835.9	0.858	7437.98 (5471.88)	-3371.1 to 18247.1	0.176
1750	881.79 (4250.70)	-7492.4 to 9255.9	0.836	7805.61 (6235.22)	-4511.4 to 20122.6	0.213
2000	1108.76 (4856.52)	-8458.9 to 10676.4	0.820	8173.24 (7011.24)	-5676.6 to 22023.2	0.246

\* WTP for a one-point improvement on the KOOS total change score from baseline to 12 months

\*\* Incremental net benefit with standard error (SE)

<sup>a</sup> A positive incremental net benefit favors the locking plate treatment group

†  $p < 0.05$ , ‡  $p \leq 0.001$

Abbreviations: WTP = willingness-to-pay, CI = confidence interval

**Table 4: Sensitivity analyses cost and effect outcomes\*.**

<b>Societal Sensitivity Analysis 1 (n = 164, CL = 106, PUD = 58)</b>							
<b>Plate</b>	<b>Cost<sup>*,a</sup></b>	<b>Δ Cost</b>	<b>CI, p-value</b>	<b>Effect<sup>*,b</sup></b>	<b>Δ Effect</b>	<b>CI, p-value</b>	<b>ICER</b>
Locking	23679.56	-5295.86	(-9792.8, -798.9) ,	21.39	+1.66	(-6.2, 2.9),	-3184.60
Non-locking	28975.42		0.02†	19.73		0.47	
<b>Societal Sensitivity Analysis 2 (n = 248, CL = 143, PUD = 105)</b>							
<b>Plate</b>	<b>Cost<sup>*,a</sup></b>	<b>Δ Cost</b>	<b>CI, p-value</b>	<b>Effect<sup>*,b</sup></b>	<b>Δ Effect</b>	<b>CI, p-value</b>	<b>ICER</b>
Locking	24214.74	-6099.77	(-9002.2, -3197.4),	21.39	+1.66	(-6.2, 2.9),	-3668.02
Non-locking	30210.06		<0.001‡	19.73		0.47	
<b>Societal Sensitivity Analysis 3 (n = 248, CL = 143, PUD = 105)</b>							
<b>Plate</b>	<b>Cost<sup>*,a</sup></b>	<b>Δ Cost</b>	<b>CI, p-value</b>	<b>Effect<sup>*,b</sup></b>	<b>Δ Effect</b>	<b>CI, p-value</b>	<b>ICER</b>
Locking	24056.14	-5858.22	(-8866.3, -2850.2),	21.39	+1.66	(-6.2, 2.9),	-3522.77
Non-locking	29808.81		<0.001‡	19.73		0.47	

\*Values are reported as means

<sup>a</sup> 2016 Canadian dollars.

<sup>b</sup> Total change Knee injury and Osteoarthritis Outcome Score (KOOS) between baseline and 12 months

† p < 0.05, ‡ p ≤ 0.001

Abbreviations: ICER = Incremental cost-effectiveness ratio, CI = confidence interval

**Table 5: Sensitivity analyses net benefit regression results.**

<b>Societal Sensitivity Analysis 1 (n = 164, CL = 106, PUD = 58)</b>			
<b>WTP*</b>	<b>Incremental net benefit</b>	<b>95% CI</b>	<b>p-value</b>
0	4238.26 (2240.09)	-186.6 to 8663.1	0.060
250	4609.59 (2419.84)	-170.3 to 9389.5	0.059
500	4980.91 (2832.09)	-613.3 to 10575.1	0.081
750	5352.24 (3393.11)	-1350.1 to 12054.6	0.117
1000	5723.56 (4041.43)	-2259.4 to 13706.5	0.159
1250	6094.89 (4741.36)	-3270.7 to 15460.4	0.201
1500	6466.22 (5473.14)	-4344.8 to 17277.2	0.239
1750	6837.54 (6225.55)	-5459.7 to 19134.8	0.274
2000	7208.87 (6991.93)	-6602.2 to 21019.9	0.304
<b>Societal Sensitivity Analysis 2 (n = 248, CL = 143, PUD = 105)</b>			
<b>WTP*</b>	<b>Incremental net benefit</b>	<b>95% CI</b>	<b>p-value</b>
0	5526.82 (1483.57)	2604.1 to 8449.6	<0.001‡
250	5753.80 (1624.82)	2552.8 to 8954.8	<0.001‡
500	5980.77 (1953.15)	2132.9 to 9828.6	0.002†
750	6207.74 (2392.75)	1493.9 to 10921.6	0.010†
1000	6424.71 (2893.34)	734.6 to 12134.8	0.027†
1250	6661.68 (3428.30)	-92.3 to 13415.7	0.053
1500	6888.65 (3983.82)	-959.7 to 14737.0	0.085
1750	7115.62 (4552.37)	-1852.9 to 16084.1	0.119
2000	7342.59 (5129.63)	-2763.1 to 17448.3	0.154
<b>Societal Sensitivity Analysis 3 (n = 248, CL = 143, PUD = 105)</b>			
<b>WTP*</b>	<b>Incremental net benefit</b>	<b>95% CI</b>	<b>p-value</b>
0	5087.07 (1539.42)	2054.4 to 8119.8	0.001‡
250	5395.57 (1675.52)	2094.7 to 8696.5	0.001‡
500	5622.54 (1992.36)	1697.5 to 9547.6	0.005†
750	5849.52 (2422.25)	1077.5 to 10621.5	0.017†
1000	6076.49 (2915.62)	332.5 to 11820.4	0.038†
1250	6303.46 (3445.29)	-484.0 to 13090.9	0.069
1500	6530.43 (3996.87)	-1343.7 to 14404.5	0.104
1750	6757.40 (4562.41)	-2230.7 to 15745.7	0.140
2000	6984.40 (5137.31)	-3136.5 to 17105.2	0.175

\* WTP for a one-point improvement on the KOOS total change score from baseline to 12 months

\*\* Incremental net benefit with standard error (SE)

<sup>a</sup> A positive incremental net benefit favors the locking plate treatment group

†  $p < 0.05$ , ‡  $p \leq 0.001$

Abbreviations: WTP = willingness-to-pay, CI = confidence interval