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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APPENDIX 1

METHODS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

RESULTS

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

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

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

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

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

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

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

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

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

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

Demographic/clinical characteristic	Group 1: Locking Plate (n = 143)	Group 2: Non-locking Plate (n = 105)
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^2	30.0 ± 5.0	29.4 ± 4.4
Operative limb left, no. (%)	76 (53.1)	52 (49.5)
Mechanical axis angle, degrees [a]	-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. (%) [b]		
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. (%) [b]		
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. (%) [c]		
1	47 (32.9)	37 (35.2)
2	82 (57.3)	54 (51.4)
3	14 (9.8)	14 (13.3)

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

[a] A negative mechanical axis value indicates varus alignment

[b] Kellgren-Lawrence (K/L) grade of osteoarthritis severity

[c] American Society of Anesthesiologists physical status classification system: 1 = healthy, normal patient; 2 = patient with mild systemic disease; 3 = patient with severe systemic disease

Table 2: Cost and effect outcomes*.

Healthcare payer (n = 248, CL = 143, PUD = 105)							
Plate	**Cost*,[a]**	**Δ Cost**	**CI, p-value**	**Effect*,[b]**	**Δ Effect**	**CI, p-value**	**ICER**
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			
Societal (n = 164, CL = 106, PUD = 58)							
Plate	**Cost*,[a]**	**Δ Cost**	**CI, p-value**	**Effect*,[b]**	**Δ Effect**	**CI, p-value**	**ICER**
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

[a] 2016 Canadian dollars.

[b] Total change Knee injury and Osteoarthritis Outcome Score (KOOS) between baseline and 12 months

† $p < 0.05$, ‡ $p \leq 0.001$

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

Table 3: Net benefit regression results.

WTP*	Healthcare payer**			Societal**		
	Incremental net benefit[a]	95% CI	p-value	Incremental net benefit[a]	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)

[a] 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*.

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

*Values are reported as means

[a] 2016 Canadian dollars.

[b] Total change Knee injury and Osteoarthritis Outcome Score (KOOS) between baseline and 12 months

† $p < 0.05$, ‡ $p \leq 0.001$

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

Table 5: Sensitivity analyses net benefit regression results.

	Societal Sensitivity Analysis 1 (n = 164, CL = 106, PUD = 58)		
WTP*	**Incremental net benefit**	**95% CI**	**p-value**
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
	Societal Sensitivity Analysis 2 (n = 248, CL = 143, PUD = 105)		
WTP*	**Incremental net benefit**	**95% CI**	**p-value**
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
	Societal Sensitivity Analysis 3 (n = 248, CL = 143, PUD = 105)		
WTP*	**Incremental net benefit**	**95% CI**	**p-value**
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)

a 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