Suture Button Fixation Versus Syndesmotic Screws in Supination–External Rotation Type 4 Injuries

A Cost-Effectiveness Analysis

Kaitlin C. Neary,*† MD, Matthew A. Mormino,† MD, and Hongmei Wang,† PhD
Investigation performed at the University of Nebraska Medical Center, Omaha, Nebraska, USA

Background: In stress-positive, unstable supination–external rotation type 4 (SER IV) ankle fractures, implant selection for syndesmotic fixation is a debated topic. Among the available syndesmotic fixation methods, the metallic screw and the suture button have been routinely compared in the literature. In addition to strength of fixation and ability to anatomically restore the syndesmosis, costs associated with implant use have recently been called into question.

Purpose: This study aimed to examine the cost-effectiveness of the suture button and determine whether suture button fixation is more cost-effective than two 3.5-mm syndesmotic screws not removed on a routine postoperative basis.

Study Design: Economic and decision analysis; Level of evidence, 2.

Methods: Studies with the highest evidence levels in the available literature were used to estimate the hardware removal and failure rates for syndesmotic screws and suture button fixation. Costs were determined by examining the average costs for patients who underwent surgery for unstable SER IV ankle fractures at a single level-1 trauma institution. A decision analysis model that allowed comparison of the 2 fixation methods was developed.

Results: Using a 20% screw hardware removal rate and a 4% suture button hardware removal rate, the total cost for 2 syndesmotic screws was US$20,836 and the total effectiveness was 5.846. This yielded a total cost of $3564 per quality-adjusted life-year (QALY) over an 8-year time period. The total cost for suture button fixation was $19,354 and the total effectiveness was 5.904, resulting in a total cost of $3294 per QALY over the same time period. A sensitivity analysis was then conducted to assess suture button fixation costs as well as screw and suture button hardware removal rates. Other possible treatment scenarios were also examined, including 1 screw and 2 suture buttons for operative fixation of the syndesmosis. To become more cost-effective, the screw hardware removal rate would have to be reduced to less than 10%. Furthermore, fixation with a single suture button continued to be the dominant treatment strategy compared with 2 suture buttons, 1 screw, and 2 screws for syndesmotic fixation.

Conclusion: This cost-effectiveness analysis suggests that for unstable SER IV ankle fractures, suture button fixation is more cost-effective than syndesmotic screws not removed on a routine basis. Suture button fixation was a dominant treatment strategy, because patients spent on average $1482 less and had a higher quality of life by 0.058 QALYs compared with patients who received fixation with 2 syndesmotic screws. Assuming that functional outcomes and failure rates were equivalent, screw fixation only became more cost-effective when the screw hardware removal rate was reduced to less than 10% or when the suture button cost exceeded $2000. In addition, fixation with a single suture button device proved more cost-effective than fixation with either 1 or 2 syndesmotic screws.

Keywords: syndesmotic injury; suture button; cost-effectiveness analysis; economic and decision analysis

Ankle fractures are one of the most common fractures treated by orthopaedic surgeons and are often accompanied by other associated injuries.[32] Syndesmotic disruption has been reported to occur in 13% of all ankle fractures and in approximately 20% of ankle fractures requiring operative fixation.[6] Although syndesmotic injury occurs most commonly in association with supination–external rotation type 4 (SER IV) mechanisms, syndesmosis disruption may be associated with any of the Lauge-Hansen fracture patterns.[4,6]

There are many factors that contribute to restoring function and achieving successful outcomes following operative

*Address correspondence to Kaitlin C. Neary, MD, Department of Orthopaedic Surgery and Rehabilitation, University of Nebraska Medical Center, 981080 Nebraska Medical Center, Omaha, NE 68198-1080, USA (email: kaitlincneary@gmail.com).

†Department of Orthopaedic Surgery and Rehabilitation, University of Nebraska Medical Center, Omaha, Nebraska, USA.

One or more of the authors has declared the following potential conflict of interest or source of funding: M.A.M. is a consultant for Cardinal Health.

The American Journal of Sports Medicine, Vol. 45, No. 1
DOI: 10.1177/0363546516664713

fixation of SER IV syndesmotic injuries. These include patient-specific factors, the quality of reduction, and fixation that is strong enough to maintain the reduction until ligamentous healing has occurred. Implant selection for syndesmotic fixation has become a debated topic in the literature. Fixation choices include metallic screw fixation, suture button devices, biodegradable implants, bolt fixation, syndesmotic hooks, staples, and direct repair.[29] Regarding screw fixation, debated issues include the number of screws across the joint, number of cortices engaged, screw size, and whether the screws should be removed routinely after a specific postoperative time period.[13] There has also been recent debate comparing syndesmotic screws versus suture button devices in terms of their ability to maintain reduction, rate of reoperation, and functional outcomes.

When evaluating outcomes following syndesmotic fixation, it is important to not only examine functional outcomes and quality of life but to also evaluate the associated cost of treatment. The goal of obtaining the highest clinical outcomes while remaining fiscally responsible has been the subject of much recent research.[1] To our knowledge, there are no studies reported in the literature evaluating the cost-effectiveness of different syndesmotic fixation methods. This study aimed to evaluate and report the cost-effectiveness of 2 common syndesmotic fixation methods: suture button fixation using the TightRope suture button (Arthrex) versus two 3.5-mm syndesmotic screws without planned routine postoperative removal.

METHODS

Design

This study followed the consensus-based recommendations made by the Panel on Cost-Effectiveness in Health and Medicine.[25,28,30,34]

We assumed the base case to be an otherwise healthy person who sustained a SER IV ankle fracture including an unstable syndesmotic injury requiring stabilization. For purposes relevant to this study, the "gold standard" syndesmotic stabilization was defined as two 3.5-mm metallic syndesmotic screws not removed on a routine postoperative basis. This gold standard treatment was then compared with fixation with a specific suture button device, the TightRope (Arthrex).

A thorough literature search was conducted to identify only studies with the highest level of evidence reporting long-term outcomes for screw and suture button fixation. This included all existing level 1 and level 2 studies, and level 3 and/or level 4 studies when higher level evidence was unavailable. This study assumed the long-term outcomes for suture button fixation to be equivalent to syndesmotic screws, as has been shown in a study by Naqvi et al[20] (level 2 evidence) in which they reported no statistically significant difference between suture button fixation and syndesmotic screws at an average 2.5-year follow-up. Laflamme et al[16] revealed comparable findings that support the assumption of similar outcomes.

A follow-up period of 8 years was chosen for the base case, because this was the longest follow-up period for screw fixation identified in the literature (evidence levels 1-4). To our knowledge, there are no current studies reporting long-term outcomes for the suture button. Therefore, an 8-year follow-up period was deemed appropriate for both options, assuming that outcomes of each fixation device were similar.

Decision Model

The model in this study was developed using decision tree analysis provided by TreeAge Pro 2015 software (TreeAge Software). A health economist at our institution confirmed the initial TreeAge calculations and performed additional calculations (including rerunning the model) to ensure accuracy of the results.

The base case was assumed to have sustained a SER IV ankle fracture with an unstable syndesmotic injury requiring operative fixation. Patients then underwent either syndesmotic fixation using a suture button or open reduction internal fixation (ORIF) using two 3.5-mm syndesmotic screws without routine removal. The patients undergoing either treatment strategy were assumed to have a similar health-related quality of life over the first year. At 1 year postoperatively, patients in both treatment groups were allocated to 1 of 3 outcomes: well, symptomatic hardware requiring hardware removal (revision), or failure. Patients who required hardware removal at the end of year 1 were assumed to either do well following hardware removal or progress to failure. Those allocated to the well group either continued to remain well or at some point also progressed to failure (Figure 1). We assumed these changes to occur over the first 4 years postoperatively and then assumed no changes in outcome from years 4 to 8. Failure was defined as progression to end-stage arthritis. Once patients entered the failure state, their outcome status did not change.

Subjects in the cohort were allocated to each of these groups based on probabilities reported in the literature. This was accomplished through the use of a Markov cohort analysis model, in which subjects were allocated to certain disease states over a specified time interval based on transition probabilities. We did not include infections, other minor complications, or revision surgery in which repeat internal fixation was required, because these were assumed to be equivalent among groups. We also assumed that those who did well after hardware removal did slightly worse compared with those who did well following their primary operation.

Hardware Removal and Failure Rates

All data were derived from a literature search aimed at identifying failure rates for both suture button fixation and syndesmotic screws without routine removal. Multiple studies with varying levels of evidence (2-4) and at least 8 months of follow-up were identified. Regarding syndesmotic screws, a systematic review by Schepers[29] reported average screw removal for symptomatic or failed hardware at 3 to 4 months postoperatively. Six different studies

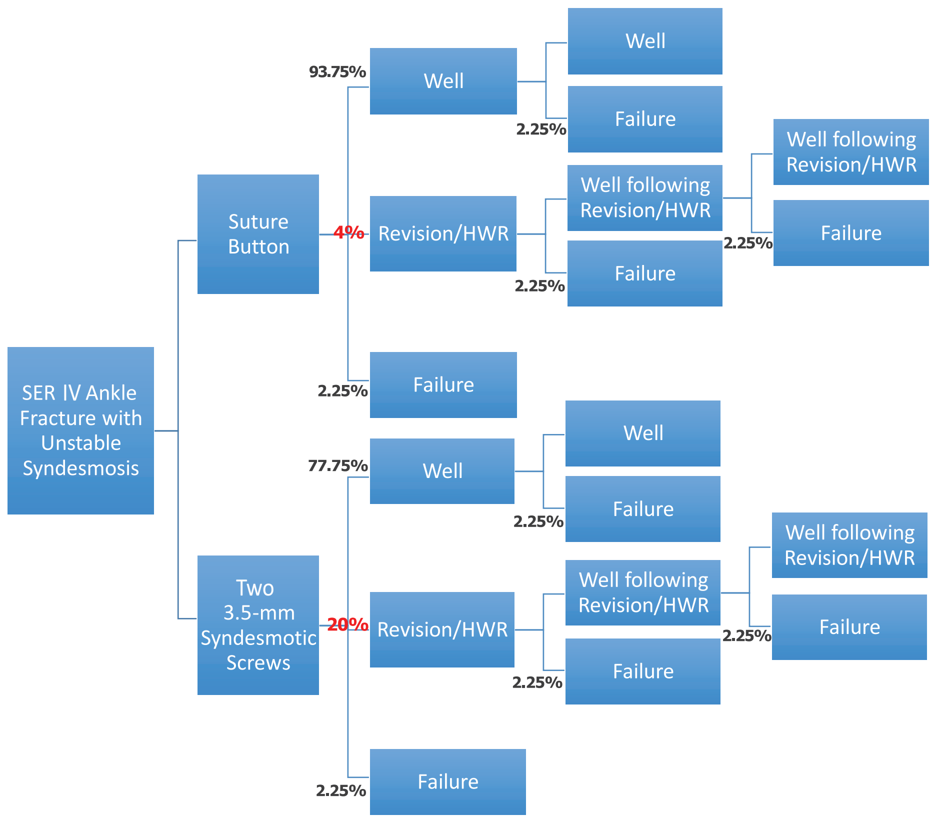

Figure 1. Decision tree outline. HWR, hardware removal; SER IV, supination–external rotation type 4.

(evidence level 2-4) were identified in which hardware removal rates for symptomatic or failed syndesmotic screws ranged from 5% to 52%.[2,10,16,19,29,33] We therefore used a value of 20% for the screw hardware removal rate secondary to symptomatic or failed hardware, which was the mean among the reported values. Regarding suture button fixation, 5 different studies (evidence level 2-4) were identified in which rates of symptomatic or failed hardware requiring removal ranged from 0% to 10%.[5,8,16,20] Once again, the mean among reported rates was used, and a 4% suture button hardware removal rate was chosen. Hardware removal was assumed to have occurred by the end of postoperative year 1.

Failure in this study was defined as progression to grade 3 or 4 arthritis. Kortekangas et al[14,15] (level 2 evidence) analyzed function and osteoarthritis following SER IV ankle fractures. A 9% incidence of grade 3/4 arthritis was reported following syndesmotic injury with a minimum 4-year follow-up. Therefore, a failure rate of 9% was chosen for our study and was assumed to have occurred by postoperative year 4; thus, the annual failure rate was set at 2.25%.

For both suture button fixation and syndesmotic screws, patients in the well group comprised the remaining participants not allocated to either the failure or revision groups. Failure rates were assumed to be the same following both primary fixation and revision. We were unable to find consistent high-level evidence suggesting differing rates of posttraumatic arthritis between suture button and syndesmotic screw fixation; therefore, we assumed that the failure rate (9% overall) was equivalent between the 2 groups.

Cost

The average direct cost for a patient undergoing operative fixation of an unstable SER IV injury was estimated based on data obtained from a single level-1 trauma institution. This included the average of all hospital, anesthesia, surgeon, intraoperative radiology, and implant fees from 5 randomly selected patients who underwent operative fixation for an unstable SER IV injury.

Surgical costs including operating room, surgeon, radiology, and anesthesia fees were estimated at US$17,726. This value was used for both fixation methods. Implant costs were obtained from local representatives with each implant company. These were the current actual listed prices, not the negotiated hospital contract cost of the implants. The cost for two 3.5-mm Synthes cortical screws was $64.50. The average cost for the Arthrex TightRope suture button was $880.00. The fibula fracture was assumed to be fixed with a one-third tubular plate in all patients, with an estimated cost of $175.00 (Table 1).

TABLE 1
Average Direct Costs Associated With Operative Fixation of Unstable SER IV Injuries, Including Surgical Costs, Revision Surgery, and Implant Pricing[a]

Item	Cost, US$
Ancillary costs/implant pricing	
Operating room, surgeon, radiology, and anesthesia fees	17,726
Two 3.5-mm syndesmotic screws	64.50
Arthrex TightRope	880.00
Eight-hole, one-third tubular plate	175.00
Total surgical costs	
ORIF with two 3.5-mm screws not routinely removed	17,969
ORIF with TightRope fixation	18,781
Revision surgery	14,768

[a]ORIF, open reduction internal fixation; SER IV, supination-external rotation type 4.

The direct cost of each procedure was derived by adding the implant cost (including the one-third tubular plate) to the estimated surgical fees. The direct costs for each procedure, therefore, totaled $17,969 for operative fixation with two 3.5-mm syndesmotic screws and $18,781 for operative fixation with a single suture button (Table 1).

Indirect costs such as durable medical equipment, physical therapy, and loss of productivity from time off work were assumed to be the same between groups and thus were not included. Time in the operating room was also assumed to be equivalent among groups secondary to similar time required for each fixation device.

A revision cost of $14,768 was assumed for those patients who developed symptomatic or failed hardware requiring removal (Table 1). This was also estimated based on the average cost of 5 patients undergoing hardware removal at a single level-1 trauma institution. This covered all hospital, surgeon, anesthesia, and intraoperative radiology fees related to operative removal of the patients' hardware. It also included 2 extra clinic visits and 1 set of ankle radiographs estimated at $309. Again, physical therapy, durable medical equipment, and loss of productivity were not included in the estimated cost.

Discounting

A discount rate of 3% was used in the present study for all estimated future costs.

Effectiveness

As a cost-effectiveness analysis, this study relied on both the cost of each treatment as well as the quality of life spent in various health states associated with each treatment. Effectiveness, being a specific measurement of the quality of life spent in a certain health state over the course of 1 year, can be represented by the quality-adjusted life-year (QALY). Although there are various ways to define and measure QALYs, we used the Health Utilities Index (HUI) to define health-related quality of life. The HUI is a measure of perceived quality of life in which values range from 1 (perfect health) to 0 (deceased). Numerical values between 1 and 0 are assigned, representing the quality of life spent in a specific health state. This HUI value is then divided by the number of years lived in that state, which will give the QALY and thus the effectiveness of that intervention. By defining effectiveness in QALYs, one can compare a variety of different conditions using a single common utility. Furthermore, cost-effectiveness can be calculated by dividing the cost of the intervention by the QALY associated with that intervention, or dollars per QALY.

TABLE 2
Health Utilities Index Values for the Present Study[a]

Health States	Health Utilities Index
Slobogean et al[31]	
Uncomplicated union	0.749
Union following implant removal	0.696
Union with complication requiring reoperation	0.686
Ankle arthritis	0.670
Current study	
Well	0.749
Well following revision/HWR	0.696
Revision/HWR	0.686
Failure	0.670

[a]Health Utilities Index values were adopted from Slobogean et al.[31] HWR, hardware removal.

We were unable to locate any studies in the literature that specifically reported health-related quality of life following unstable syndesmotic injury using HUI values or QALYs. Comparatively, Slobogean et al[31] conducted a cost-effectiveness analysis evaluating operative versus nonoperative treatment of all unstable Weber B ankle fractures (with or without syndesmotic injury), in which the Short Form–36 Health Survey (SF-36) data were converted into SF-6D HUI values. At 1 year, HUI values were reported at 0.749 for an uncomplicated union, 0.696 for a union with implant removal, 0.686 for a union with a complication requiring reoperation, and 0.670 for ankle arthritis.[31] For our study, we assumed that these utility values were similar to those that would be obtained for unstable syndesmotic injuries; therefore, we used these values as measures of effectiveness (Table 2). We also assigned each subject in the cohort to begin with a preoperative health utility value of 0.67, assuming that preoperative health states were similar to those experienced with progression to end-stage arthritis.

The findings by Slobogean et al[31] were consistent with other health-related quality of life studies reported in the literature. Saltzman et al[27] examined the effect of comorbidities on quality of life in patients with ankle osteoarthritis. They found no difference in SF-36 scores (health outcome measure) between patients with ankle arthritis and those with other chronic conditions, including end-stage renal disease, congestive heart failure, and cervical spine radiculopathy. A study by Davison et al[7] reported an average HUI value of 0.66 (HUI2/HUI3 average score) for chronic kidney disease. This is consistent with the findings by Slobogean et al, in which an HUI score of 0.670 was assigned to ankle arthritis, further validating the use of this value for arthritis for both treatment groups in our study.

We used the incremental cost-effectiveness ratio (ICER) as the measure of cost-effectiveness. The ICER is the ratio of the mean incremental cost and the mean incremental effectiveness (in dollars per QALY) of the more effective option. The ICER serves as a reflection of the cost-effectiveness of a specific intervention and provides a numeric value to which other treatment strategies may be compared.

Sensitivity Analysis

When calculating cost-effectiveness and ICERs, it is important to remember that the final obtained value is based on many assumptions and estimations derived from the highest available literature. Therefore, there is always a degree of uncertainty in the final outcome, which may vary based on different parameter values. Sensitivity analysis is a way to evaluate how the outcome may change by varying the value of a single parameter. It is ultimately a measure of how sensitive the model is to a particular uncertainty. If the model outcome proves to be sensitive to different values for a single parameter, the values of the parameter at which the outcome of the model changes are able to be identified.

In the present study, multiple variables were chosen for sensitivity analysis in order to evaluate the uncertainty of the reported results. The chosen variables included the cost of the suture button, screw and suture button hardware removal rates, and other possible treatment scenarios including 1 screw versus 1 suture button, 2 screws versus 2 suture buttons, and 1 screw versus 2 suture buttons. It should be noted that effectiveness was assumed to be equivalent among each of these scenarios; therefore, only the costs associated with each implant device were varied. Furthermore, because effectiveness and progression to end-stage arthritis were assumed to be equivalent among groups, both failure rates and HUI values for each health state were not included in the sensitivity analysis.

RESULTS

Base Case

In this study, the total cost for treatment with 2 syndesmotic screws was $20,836 and the total effectiveness was 5.816 QALYs over the 8-year time period. The total cost for treatment with suture button fixation was $19,354 and the total effectiveness was 5.874 QALYs over the same time period (Figure 2). This subset of patients spent on average $1482 less and had a higher quality of life by 0.058 QALYs over the 8-year postoperative time period. This was further reflected by calculation of the cost per QALY (dollars per QALY), in which suture button fixation ($3294/QALY) was more cost-effective than 2 syndesmotic screws ($3583/QALY) (Table 3).

When attempting to calculate the ICER ([*Cost of TightRope* – *Cost of 2 screws*]/[*Effectiveness of TightRope* – *Effectiveness of 2 screws*]) in the present study, a negative value was encountered. This effectively identifies syndesmotic screws as a dominated treatment variable. In cost-effectiveness analyses, a dominated variable is one in which the comparison variable is not only more effective, it is also less expensive. Dominated variables are therefore eliminated from cost-effectiveness analyses, as they pose no financial or functional outcome benefit when compared to the other variables. Extending these same principles to the present study, it can be concluded that the benefits gained by TightRope fixation outweigh the benefits gained for syndesmotic screw intervention, as represented by a negative ICER.

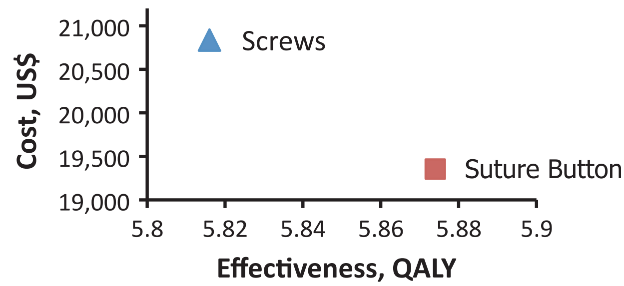

Figure 2. Results of cost-effectiveness analysis revealing suture button fixation to be both more effective and less expensive. QALY, quality-adjusted life-year.

TABLE 3
Results for Cost and Effectiveness of Two 3.5-mm Screws and Suture Button Fixation[a]

	One TightRope	Two 3.5-mm Screws
Total cost, US$	19,354	20,836
Total effectiveness	5.874	5.816
$/QALY	3294	3583

[a]QALY, quality-adjusted life-year.

Sensitivity Analysis

A sensitivity analysis was performed to examine cost as well as the probability of screw and button hardware removal.

Cost. In the base case, the cost of the suture button was $880. A sensitivity analysis was performed in which the cost of the suture button was varied from $880 to $2000, keeping all other variables the same. Sensitivity analysis revealed that the suture button remained more cost-effective even at a cost of $2000, with a total cost of $20,475 (compared with $20,837 for the baseline screws) and total effectiveness of 5.874 (compared with 5.816 for the baseline screws). Therefore, suture button fixation remained less expensive than syndesmotic screws by $362. The suture button would have to cost more than $2000 in order for the screws to become the more cost-effective option.

Probability of Screw and Suture Button Hardware Removal. In the literature, screw hardware removal rates varied from 5% to 52%. In our study, we used the mean (20%) as the screw hardware removal value. Therefore,

TABLE 4
Comparison of Cost, Effectiveness, and Dollars per QALY for Each Treatment Scenario[a]

	One TightRope	Two TightRopes	One 3.5-mm Screw	Two 3.5-mm Screws
Total cost, US$	19,354	20,235	20,803	20,836
Total effectiveness	5.874	5.874	5.816	5.816
$/QALY	3294	3445	3576	3583

[a]Treatments are shown in decreasing order of cost-effectiveness from left to right. QALY, quality-adjusted life-year.

using a minimum value of 5% and a maximum value of 10%, screw hardware removal rates were varied and sensitivity analysis was performed. We found that with a 10% screw hardware removal rate, the total cost dropped to $19,402 and the total effectiveness increased to 5.852 ($3315/QALY). With a 5% screw hardware removal rate, the cost dropped to $18,686 and the total effectiveness increased to 5.870 ($3183/QALY). Compared with $3294/QALY for the suture button, there would have to be a less than 10% screw hardware removal rate in order for syndesmotic screws to become the more cost-effective option.

The same analysis was then conducted for suture button hardware removal rates, which ranged from 0% to 10% in the literature. With a hardware removal rate of 10%, the total cost increased to $20,215 and the total effectiveness decreased to 5.852. At a 10% hardware removal rate, the suture button continued to be a dominant treatment choice because it remained more cost-effective by $622 and resulted in higher quality of life by 0.037 QALYs. Therefore, even when using the highest reported hardware removal rate in the literature (10%), the suture button remained the more cost-effective option (assuming a screw hardware removal rate of 20%).

Comparison of Other Common Treatment Scenarios

Although the primary focus of our study was to compare 2 screws versus 1 suture button, we also compared other possible treatment scenarios. This included 1 screw versus 1 suture button, 2 screws versus 2 suture buttons, and 1 screw versus 2 suture buttons. We assumed effectiveness to be equivalent among each of these scenarios, and only the costs associated with each implant device were varied. When comparing 1 screw versus 1 suture button, 1 suture button continued to not only be less expensive by $1448 but was also more effective by 0.058 QALYs. In the scenario of 2 suture buttons versus 2 screws, 2 suture buttons were also more effective by 0.058 QALYs and less expensive by $602. In addition, 2 suture buttons continued to be more cost-effective than 1 screw, with a difference of $568 and, once again, more effective by 0.058 QALYs (Table 4). The results reveal that although 1 suture button is more cost-effective than 2 suture buttons, both suture button options prove to be more cost-effective than either 1 or 2 screws for syndesmotic fixation.

DISCUSSION

Ankle fractures are a common orthopaedic injury and treatment strategies have long been debated. Surgery not only takes a physical toll, but it can also be a financial burden. When examining the cost utility regarding operative fixation for unstable ankle fractures, Bhandari et al[1] reported that patients treated operatively can be expected to show improvement in health-related quality of life up to 1 year after surgery at an acceptable cost. This was supported by a more recent study by Slobogean et al[31] that also examined the cost-effectiveness of surgical fixation for stress-positive unstable ankle fractures. Slobogean et al found that if operative fixation decreases the lifetime incidence of posttraumatic arthritis by >3%, then ORIF becomes more cost-effective.

Although studies show the financial advantage of surgical management for ankle fractures, it is still prudent to consider the associated costs when evaluating potential treatment options. This is of particular importance when considering implant choice. In this study, it was suggested that suture button fixation for unstable SER IV ankle fractures with syndesmotic injury is not only the more effective option, but it is also less expensive over an 8-year time period. Both 1 and 2 syndesmotic screws were found to be dominated variables compared with suture button fixation. In a cost-effectiveness analysis, a dominated variable is one that is not only more costly but also less effective than the treatment option to which it is being compared. This is an important finding in cost-effectiveness analysis because these dominated treatment strategies are often eliminated based on their relatively low utility and increased cost compared with other variables.

Although our findings suggest that suture button fixation is the more cost-effective option, it is important to remember that this conclusion is based on a number of estimated values. In our study, a screw hardware removal rate of 20% was estimated based on reported values in the literature. When the screw hardware removal rate was decreased to 5% and all other variables were kept the same, screw fixation became the more cost-effective option. Furthermore, as the cost of suture button fixation increased, the 2 options grew more similar in regard to cost. Therefore, whenever estimated variables are used in cost-effectiveness analysis, one must use caution when interpreting the results because these may differ widely as the parameters are varied.

Although our study examines the cost-effectiveness of 2 different fixation devices, outcomes following syndesmotic fixation are dependent on other factors as well. Many studies have shown that the quality of reduction during surgery is a significant factor contributing to the development of posttraumatic arthritis and poor clinical outcomes following syndesmotic injury. Patients with anatomically reduced fractures tend to be at lower risk for unfavorable outcomes compared with those with poor reductions.[11] Sagi et al[26] showed that up to 40% of syndesmoses are malreduced postoperatively. Therefore, it is imperative not only to achieve anatomic reduction of the syndesmosis intraoperatively but also to use a reliable implant with low likelihood of hardware failure or loss of reduction.

Multiple studies have documented various complications associated with screw fixation. These complications include late syndesmotic widening after screw removal and the potential need for a second operation for screw removal secondary to screw breakage or loosening, symptomatic hardware, or as part of a postoperative protocol where routine screw removal is performed.[3,5,9,16,18] Rigid fixation with metallic screws may inhibit physiologic motion within the syndesmosis, leading to abnormal biomechanics of the ankle joint.[22,23] Furthermore, patients with broken syndesmotic screws are shown to often have better clinical outcomes than individuals with screws that remain intact, and some studies have even suggested no overall functional improvement with the addition of syndesmotic screws.[12,17,24] This has led to growing interest in the pursuit of other treatment options for syndesmotic disruption.

In an attempt to avoid these complications, suture button fixation has recently been the focus of much research. Studies in the literature report many advantages of suture button fixation for unstable syndesmotic injuries. The suture button provides less rigid fixation compared with screws, which is thought to allow more physiologic motion within the joint. In theory, this leads to less pain secondary to more anatomic reduction and motion of the syndesmosis.[5] Furthermore, because suture button fixation provides flexibility while also maintaining adequate strength, early mobilization may also be allowed with minimal risk of redisplacement or hardware failure. Theoretically, there is also a smaller risk of symptomatic or failed hardware and thus a lower rate of reoperation and implant removal.[16,21,29]

Although multiple advantages have been cited, there are also disadvantages associated with suture button fixation. Rare adverse effects have been reported, including infection, overlying skin irritation, local inflammatory reactions from the suture button, and granuloma formation that may warrant hardware removal. That said, the biggest disadvantage of suture button fixation is likely the cost of the device compared with standard 3.5-mm metallic screws. Despite the difference in cost, some believe this is offset by the lower reoperation rate compared with other methods of fixation.[16]

This study has some limitations. First, only the failure and hardware removal rates of each treatment strategy were derived from the literature. The remaining percentage of the cohort was placed in the "well" category, thus providing an estimate of the probability of a good outcome. In other words, if patients did not develop end-stage arthritis (failure) or require a second operation (hardware removal), they were assumed to do well. Realistically, there is a group of patients in which outcomes are less than favorable following surgery but no further treatment is sought. This was not accounted for in the present study. Second, we did not factor in cost associated with patients who may seek surgical treatment options for failure, such as arthrodesis secondary to posttraumatic arthritis. For patients who underwent such an operation within our specified 8-year time period, this would likely affect the overall cost of the model. Third, the failure rates (progression to posttraumatic arthritis) were assumed to be equivalent at 9% for both modes of fixation, but this did not account for the severity of injury. It is probable that more severe injuries would be more likely to progress to failure, which could also affect the health-related quality of life associated with that injury. This study also does not account for individuals who developed asymptomatic arthritis. We also assumed all indirect costs such as loss of productivity, time off work, durable medical equipment, physical therapy, outpatient clinic visits, and outpatient radiology to be equivalent among groups undergoing the primary surgery; therefore, these costs were not factored into the overall cost. We did, however, factor in 2 outpatient clinic visits and 1 extra set of radiographs for the cost of the revision group. The extra cost was minimal at $309 and therefore was unlikely to have much of an effect on the results. The costs associated with each specific procedure were also estimated to the best of our abilities. That said, costs for each operation will vary depending on geographic location, hospital contracts, and surgeon experience. Therefore, the costs in our study may not be truly representative of the group as a whole. Finally, HUI values were also estimated based on the highest available literature. We chose to estimate these values because, to our knowledge, there are no available studies reporting the HUI values specifically regarding SER IV ankle fractures with syndesmotic disruption.

The most significant limitation, as stated above, is the fact that the outcome of this study stems from estimated parameters and values. This is a common limitation in cost-effectiveness analysis and is often cited as a drawback in such studies. That said, sensitivity analysis allows these parameters to be varied while monitoring the effect on outcome. Therefore, even when values are estimated, one is able to observe the sensitivity of the model to changes in certain parameters.

Another potential limitation was the assumption that outcomes (HUI values) are equivalent between suture button and screw fixation. This has been a much debated topic, with multiple studies reporting conflicting results regarding outcomes.[5,15,16,20] Naqvi et al[21] compared TightRope versus syndesmotic screw fixation and found no significant difference between reported outcomes at 2.5 years (level 2 evidence). Kortekangas et al[15] obtained similar findings; neither the incidence of ankle posttraumatic arthritis nor functional outcomes differed significantly between fixation methods at 2 years. This was further supported by Cottom et al,[5] who also found no clinical difference between fixation options at 6 months postoperatively.

Conversely, in a recent multicenter, randomized, double-blind controlled trial (level 2 evidence) comparing dynamic (suture button) versus static (screw) fixation, Laflamme et al[16] found that patients with dynamic fixation had higher clinical outcome scores and a lower rate of implant failure at 12 months. Consequently, significant lack of agreement remains in the literature surrounding functional outcomes when comparing suture button versus screw fixation.

We also elected to not include syndesmotic screws removed on a planned, routine postoperative basis in our analysis. We assumed that with a 100% reoperation rate, this treatment option would prove less cost-effective than both suture button fixation and syndesmotic screws that are not routinely removed. Furthermore, we also did not include screws removed under local anesthesia in a clinical setting. This would obviously have a considerable effect on the results, because the cost of removing screws in the office under local anesthesia would be significantly less expensive than hardware removal in the operating room. Therefore, these treatment options were omitted from the present study.

CONCLUSION

Although our findings suggest suture button fixation to be the more cost-effective option, sensitivity analysis revealed that as the probability of screw hardware removal rates decreases, the difference in cost-effectiveness between screws and suture button fixation becomes less significant. Therefore, the degree to which each treatment strategy prevails will depend on many variables. These include the probability of hardware removal and failure rates for each implant, cost of the implant, and patient-specific functional outcomes. It is hoped that our findings will serve as an adjunct in the decision-making process for implant selection for unstable syndesmotic injuries in the future.

REFERENCES

1. Bhandari M, Sprague S, Ayeni OR, et al. A prospective cost analysis following operative treatment of unstable ankle fractures. *Acta Orthop Scand*. 2004;75(1):100-105.
2. Boyle M, Gao R, Frampton C, et al. Removal of the syndesmotic screw after the surgical treatment of a fracture of the ankle in adult patients does not affect one year outcomes. *Bone Joint J*. 2014;96(12):1699-1705.
3. Brown O, Dirschl D, Obremskey W. Incidence of hardware-related pain and its effect on functional outcomes after open reduction and internal fixation of ankle fractures. *J Orthop Trauma*. 2001;15(4):271-274.
4. Close JR. Some applications of the functional anatomy of the ankle joint. *J Bone Joint Surg Am*. 1956;38(4):761-781.
5. Cottom J, Hyer C, Philbin T, et al. Transosseous fixation of the distal tibiofibular syndesmosis: comparison of an interosseous suture and endobutton to traditional screw fixation in 50 cases. *J Foot Ankle Sur*. 2009;48(6):620-630.
6. Dattani R, Patnaik S, Kantak A, et al. Injuries to the tibiofibular syndesmosis. *J Bone Joint Surg Br*. 2008;90(4):405-410.
7. Davison S, Jhangri G, Feeny D. Evidence on the construct validity of the health utilities index mark 2 and mark 3 in patients with chronic kidney disease. *Qual Life Res*. 2008;17(6):933-942.
8. Degroot H, Al-Omari A, Ghazaly S. Outcomes of suture button repair of the distal tibiofibular syndesmosis. *Foot Ankle Int*. 2011;32(3):250-256.
9. Den Daas A, Van Zuren W, Pelet S, et al. Flexible stabilization of the distal tibiofibular syndesmosis: clinical and biomechanical considerations: a review of the literature. *Strategies Trauma Limb Reconstr*. 2012;7(3):123-129.
10. Egol K, Pahk B, Walsh M, et al. Outcome after unstable ankle fracture: effect of syndesmotic stabilization. *J Orthop Trauma*. 2010;24(1):7-11.
11. Finnan R, Funk L, Pinzur M, et al. Health related quality of life in patients with supination-external rotation stage IV ankle fractures. *Foot Ankle Int*. 2005;26(12):1038-1041.
12. Hamid N, Loeffler B, Braddy W, et al. Outcome after fixation of ankle fractures with an injury to the syndesmosis. *J Bone Joint Surg Br*. 2009;91(8):1069-1073.
13. Hoiness P, Stromsoe K. Tricortical versus quadricortical syndesmosis fixation in ankle fractures. *J Orthop Trauma*. 2004;18(6):331-337.
14. Kortekangas T, Flinkkila T, Niinimaki J, et al. Effect of syndesmosis injury in SER IV (Weber B)-type ankle fractures on function and incidence of osteoarthritis. *Foot Ankle Int*. 2015;36(2):180-187.
15. Kortekangas T, Pakarinen H, Savola O, et al. Syndesmotic fixation in supination-external rotation ankle fractures: a prospective randomized study. *Foot Ankle Int*. 2014;35(10):988-995.
16. Laflamme M, Belzile E, Bedard L, et al. A prospective randomized multicenter trial comparing clinical outcomes of patients treated surgically with a static or dynamic implant for acute ankle syndesmosis rupture. *J Orthop Trauma*. 2015;29(5):216-223.
17. Manjoo A, Sanders D, Tieszer C, et al. Functional and radiographic results of patients with syndesmotic screw fixation: implications for screw removal. *J Orthop Trauma*. 2010;24(1):2-6.
18. Miller A, Paul O, Boraiah S, et al. Functional outcomes after syndesmotic screw fixation and removal. *J Orthop Trauma*. 2010;24(1):12-16.
19. Moore J, Shank J, Morgan S, et al. Syndesmosis fixation: a comparison of three and four cortices of screw fixation without hardware removal. *Foot Ankle Int*. 2006;27(8):564-572.
20. Naqvi G, Cunningham P, Lynch B, et al. Fixation of ankle syndesmotic injuries: comparison of TightRope fixation and syndesmotic screw fixation for accuracy of syndesmotic reduction. *Am J Sports Med*. 2012;40(12):2828-2835.
21. Naqvi G, Shafqat A, Awan N. TightRope fixation of ankle syndesmosis injuries: clinical outcome, complications, and technique modification. *Injury*. 2012;43(6):838-842.
22. Needleman R, Skrade D, Stiehl J. Effect of the syndesmotic screw on ankle motion. *Foot Ankle*. 1989;10(1):17-24.
23. Olerud C, Molander H. A scoring scale for symptom evaluation after ankle fracture. *Arch Orthop Trauma Surg*. 1984;103(3):190-194.
24. Pakarinen H, Flinkkila T, Ohtonen P, et al. Syndesmotic fixation in supination-external rotation ankle fractures: a prospective randomized study. *Foot Ankle Int*. 2011;32(12):1103-1109.
25. Russell L, Gold M, Siegel J, et al. The role of cost-effectiveness analysis in health and medicine. *JAMA*. 1996;276(14):1172-1177.
26. Sagi C, Shah A, Sanders R. The functional consequences of syndesmotic joint malreduction at a minimum 2 year follow up. *J Orthop Trauma*. 2012;26(7):439-443.
27. Saltzman C, Zimmerman B, O'Rourke M, et al. Impact of comorbidities on the measurement of health in patients with ankle osteoarthritis. *J Bone Joint Surg Am*. 2006;88(11):2366-2372.
28. Samuelson E, Brown D. Cost-effectiveness analysis of autologous chondrocyte implantation: a comparison of periosteal patch versus type I/III collagen membrane. *Am J Sports Med*. 2012;40(6):1252-1258.
29. Schepers T. Acute distal tibiofibular syndesmosis injury: a systematic review of suture-button versus syndesmotic screw repair. *Int Orthop*. 2012;36(6):1199-1206.
30. Siegel J, Weinstein M, Russell L, et al. Recommendations for reporting cost-effectiveness analyses. *JAMA*. 1996;276(16):1339-1341.
31. Slobogean G, Marra C, Sadatsafavi M, et al. Is surgical fixation for stress-positive unstable ankle fractures cost-effective? Results of a multicenter randomized control trial. *J Orthop Trauma*. 2012; 26(11):652-658.
32. Thur C, Edgren G, Jansson K, et al. Epidemiology of adult ankle fractures in Sweden between 1987 and 2004. *Acta Orthop*. 2012;83(3):276-281.
33. Weening B, Bhandari M. Predictors of functional outcome following transsyndesmotic screw fixation of ankle fractures. *J Orthop Trauma*. 2005;19(2):102-108.
34. Weinstein M, Siegel J, Gold M, et al. Recommendations of the panel on cost-effectiveness in health and medicine. *JAMA*. 1996;276(15): 1253-1258.