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Open reduction and internal fixation (ORIF) versus ORIF and primary subtalar arthrodesis for complex displaced intraarticular calcaneus fractures

An expected value decision analysis

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Abstract

Objectives: To determine the optimal patient-oriented treatment between open reduction and internal fixation (ORIF) with or without primary subtalar arthrodesis (PSTA) for patients with displaced intraarticular calcaneus fractures (DIACFs, OTA 82-C3 and C4).

Design: Expected value decision analysis.

Setting: Academic military treatment facility

Participants: One hundred randomly selected volunteers.

Intervention: Hypothetical clinical scenario involving ORIF versus ORIF with PSTA.

Main outcome measurements: Decision analysis was used to elucidate the superior treatment option based on expected patient values, composed of: the product of the average outcome probabilities established by previously published studies and the average ascribed patient utility values for each outcome probability. One-way sensitivity analysis was performed to quantify the amount of change required for the inferior treatment to equal or surpass the superior option.

Results: Expected values for ORIF and ORIF with PSTA were 8.96 and 18.06, respectively, favoring ORIF with PSTA. One-way sensitivity analysis was performed by artificially decreasing the rate of secondary fusion following isolated ORIF thus increasing its overall expected value. Adjusting the rate of secondary fusion to 0%, the expected value of ORIF with PSTA nearly doubled that of ORIF (18.06 vs 9.45). Similarly, when adjusting the moderate and severe complication rates following ORIF with PSTA to 100%, the expected value of ORIF with PSTA still exceeded that of ORIF (15.45 vs 8.96, and 13.52 vs 8.96, respectively).

Conclusion: Expected value decision analysis favors ORIF with PSTA as the optimal treatment for complex DIACF.

Abbreviations: DIACF = Displaced Intraarticular Calcaneus Fracture, ORIF = Open Reduction Internal Fixation, PSTA = Primary Subtalar Arthrodesis.

Keywords: arthrodesis, calcaneus fracture, displaced, intraarticular, open reduction internal fixation

1. Introduction

The optimal treatment of DIACFs, OTA 82-C3 and C4, has been scrutinized over the past few decades and to date remains controversial.[1] Although these injuries were traditionally managed nonoperatively, ORIF has gained increasing support within the contemporary literature, demonstrating improved functional outcomes through restoration of subtalar joint congruity and calcaneal height, width, and valgus alignment.[2–8] However, despite the quality of articular reduction, nearly one-fifth to one-half of patients who undergo isolated ORIF for complex DIACF may subsequently require delayed subtalar arthrodesis, often experiencing inferior results as compared to PSTA.[5,9–13] Whether patients with complex DIACFs (OTA classification 82-C3 and C4, Sanders types III and IV) should undergo ORIF with or without PSTA is a topic of debate for which there is little empiric evidence favoring one decision over the other.

The relatively low incidence of these complex fractures compounds the difficulty in studying the optimal management strategy through high-quality studies, with most series having limited number of patients and incomplete comparisons between different indications for PSTA.[9,11,12,14–16] The expected value decision analysis is a validated tool that can be used to evaluate the treatment options in complex medical decision-making scenarios such as this.[17–20] By this method, clinical evidence (probabilities of various outcomes following different procedures that are pooled through a review of the literature) is combined with patient value (utility values assigned to the various outcome

The authors have no conflicts of interest to disclose. This article was partially funded by an OTA Award, based on the merit of the submission.

The views expressed in this article are those of the author(s) and do not reflect the official policy of the Department of Army, Department of Defense, or U.S. Government.

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OTA (2018) e005

Received: 15 January 2018 / Accepted: 20 April 2018

http://dx.doi.org/10.1097/OI9.0000000000000005

probabilities indicating the degree to which the patient does or does not desire a specific outcome), yielding a quantitative overall expected value for each of the opposing clinical scenarios. A sensitivity analysis is then performed to discern the threshold for selecting a specific treatment.

The purpose of our investigation was to determine the optimal decision between ORIF with and without PSTA for patients with displaced intraarticular calcaneus fractures. We hypothesized that patients would associate a significantly greater expected value with ORIF and PSTA given the substantially lower rates of secondary fusion and comparable overall complication rates.

2. Methods

We followed the 5-step expected value decision analysis validated by previous authors, including: creation of a decision tree; ascertaining outcome probabilities; determining patient outcome utility values; performing fold-back analysis to yield overall expected values for each opposing clinical scenario; and subsequently performing a sensitivity analysis.[17–20]

2.1. Step 1: Creation of a decision tree

A decision tree was first developed to evaluate ORIF versus ORIF with PSTA for DIACF, OTA 82-C3 and C4 (Sanders types III and IV). For each treatment, 6 outcomes were established, consisting of minor, moderate, and severe complications, implant removal, and secondary fusion, as well as a state of wellness (Fig. 1). The "well" category entailed the ability to return to the previous activity or employment. Minor complications were defined as those which did not require additional medical or surgical treatment such as dysesthesia, malposition of implants that did not necessitate revision, or late compartment syndrome that was observed. Moderate complications were defined as those that required further medical management but did not necessitate reoperation, including wound complications managed with local wound care or thromboembolic events treated medically. Finally, severe complications were those requiring reoperation or revision surgery such as for malunion, nonunion, or deep infection. We established separate categories for removal of symptomatic implants as well as secondary fusion procedures. Each of these categories was mutually exclusive of each other as well as the "severe" category.

2.2. Step 2: Establishment of outcome probabilities

A comprehensive review of the literature was performed utilizing PubMed, Medline, and Cochrane databases using the following combinations of search terms: "comminuted displaced intraarticular calcaneus fracture," "Sanders III and IV calcaneus fracture," "open reduction internal fixation," and "primary subtalar arthrodesis." Articles were included that were peer-reviewed clinical studies of levels I to IV evidence, published in the English language, involving complex DIACFs, and reporting clinical outcomes of interest for isolated ORIF, ORIF + PSTA, or both. Papers that did not differentiate between simple (OTA 82-C1 and C2) and complex (OTA 82-C3 and C4) fracture patterns or that were nonspecific in their descriptions were scrutinized for their applicability based on the ability of pertinent data extraction. The primary investigators additionally reviewed references of each article. The probabilities of each of the 6 aforementioned outcomes were extracted from each paper and pooled.

2.3. Step 3: Determination of patient outcome utilities

We surveyed 100 consecutive randomly selected volunteers for their outcome preferences. Individuals who presented to our orthopaedic clinic for routine unrelated visits were given the opportunity to fill out a survey at check in. Exclusion criteria consisted of patients who were <18 years of age and those undergoing or previously underwent treatment for a DIACF. Patients who had previously undergone treatment for a DIACF were excluded as to avoid bias in answering the questionnaire. Volunteers were assumed to be otherwise healthy as no personal information or health information such as that pertaining to comorbidities was recorded. Each volunteer was asked to rate his or her preference, or ascribed utility value, for various frequencies of outcomes of interest using a visual analog scale (range 0–10, with 0 corresponding to the lowest desire for the outcome conceived by the patient and 10 as the highest desire). The average response for each outcome category was assigned as the utility value. Participants received a brief introductory description prior to completion of the survey and did not consult with a healthcare provider either before or during its completion (Fig. 2).

2.4. Step 4: Fold-back analysis

Fold-back analysis, composed of the sum of the products of the pooled probabilities and respective patient outcome utilities for each opposing scenario, was performed, yielding the overall expected values for each. The option with the highest expected value is considered the superior option.

2.5. Step 5: Sensitivity analysis

We then performed one-way sensitivity analysis to quantify the degree to which a given outcome probability must be adjusted for the inferior option to equal or surpass the established superior treatment option. As the probability (established by the pooled probabilities from the included literature) of a negative outcome is artificially increased, there is a reciprocal decrease in the expected value of that treatment. Similarly, as the probability of the negative outcome is artificially decreased, there is a reciprocal increase in the expected value of that treatment. This also helps to minimize sampling bias. One-way sensitivity analysis was performed specifically for secondary fusion rates associated with ORIF, as well as moderate and severe complication rates of ORIF and PSTA, given the associated large differences in patient utility values. Fold-back and sensitivity analyses were performed using Microsoft Office Excel 2010 (Microsoft, Redmond, Washington).

3. Results

3.1. Literature review

Review of the literature yielded 25 studies that met inclusion criteria.[2–6,9–12,14,15,21–34] From these, we extracted and subsequently pooled probabilities for each outcome of interest.

3.2. Outcome probabilities

The pooled outcome probabilities following isolated ORIF were determined to be 76.8% well, 20.0% minor complications, 13.2% moderate complications, 6.1% severe complications, 14.5% secondary fusion, and 16.3% implant removal. Pooled outcome probabilities following ORIF with PSTA were as follows: 81.4% well, 14.4% minor complications, 7.5% moderate complications, 16.6% severe complications, 0% secondary fusion, and 20.4% secondary implant removal.

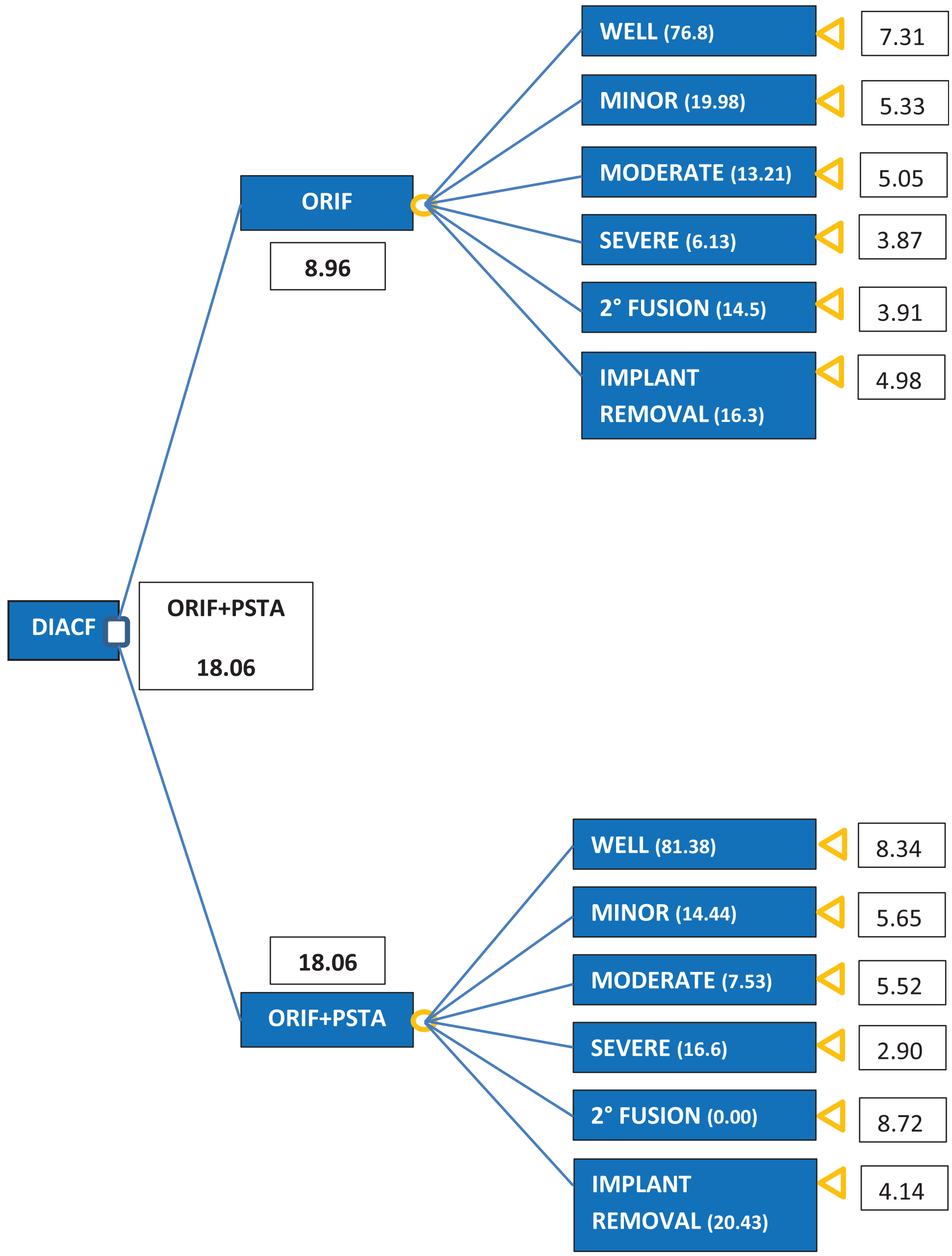

Figure 1. Decision tree with utility values, outcome probabilities, and expected values. 2°, secondary fusion, ORIF+PSTA secondary fusion expected value calculated as 100% chance of NOT having a secondary fusion to give a result other than 0.

3.3. Patient utility values

Patient preferences for each of the respective outcomes were averaged: well, 7.31 for ORIF and 8.34 for ORIF+PSTA; minor complications, 5.33 for ORIF and 5.65 for ORIF with PSTA; moderate complications, 5.05 for ORIF and 5.52 for ORIF with PSTA; severe complications, 3.87 for ORIF and 2.90 for ORIF with PSTA; secondary fusion, 3.91 for ORIF and 8.72 for ORIF with PSTA; and implant removal, 4.98 for ORIF and 4.14 for ORIF with PSTA.

3.4. Fold-back decision analysis

The fold-back analysis demonstrated ORIF with PSTA to be superior to isolated ORIF, with overall expected values of 18.06 and 8.96, respectively (Fig. 1). An example calculation for ORIF is as follows. The average response to question 1 from the 100 healthy volunteers surveyed (the patient ascribed utility value) was 7.31, and our literature review indicated an average probability of being "well" if treated with ORIF of 76.8%. We multiply 7.31×0.768 and get an expected patient value of 5.6 for the "well" outcome category for the ORIF treatment option. For the "minor" category the average patient ascribed utility value was 5.33, this multiplied by the average probability of a minor complication when treated with ORIF of 19.98% returns an expected patient value of 1.07. This same calculation is repeated for the other categories (avg patient ascribed utility value × average probability of outcome occurring = expected patient value): moderate ($5.05 \times 13.2\% = 0.67$), severe ($3.87 \times 6.13\% = 0.24$), secondary fusion

Please provide a number to answer the following questions. Please DO NOT identify yourself on this sheet. When finished, please place your answer sheet in the box. Thank you for your time in helping with this study. Your contributions will help expand the knowledge base of Orthopaedic Surgery.

Displaced Intra Articular Calcaneus Fractures (DIACF)

Background: DIACF are very rare high energy fractures of the heel bone. There are currently two ways to treat these fractures: fix them or fix them and fuse the heel bone at the same time. Sometimes, when these fractures are only fixed and not fused, patients still end up getting a fusion later on (also called secondary fusion), and sometimes those who are fixed and fused still go on to secondary fusion. We are trying to find out which method is better. For the purposes of this survey “well” means you return to your previous activities, a “mild” complication does not require any additional care besides observation, a “moderate” complication requires additional non operative care such as taking a medication or needing wound care/special dressing changes, a “severe” complication requires an additional surgery (except for a secondary fusion or removal of the operative hardware).

1: On a scale of 0-10 (10 being the most you would want to have the specific condition listed), how much would you like to have a surgery that has a 76.8% chance of being “well”? _____

2: On a scale of 0-10 (10 being the most you would want to have the specific condition listed), how much would you like to have a surgery that has an 81.4% chance of being “well”? _____

3: On a scale of 0-10 (10 being the most you would want to have the specific condition listed), how much would you like to have a surgery that has a 20% chance of a “mild” complication? _____

4: On a scale of 0-10 (10 being the most you would want to have the specific condition listed), how much would you like to have a surgery that has a 14.4% chance of a “mild” complication? _____

5: On a scale of 0-10 (10 being the most you would want to have the specific condition listed), how much would you like to have a surgery that has a 13.2% chance of a “moderate” complication? _____

6: On a scale of 0-10 (10 being the most you would want to have the specific condition listed), how much would you like to have a surgery that has a 7.5% chance of a “moderate” complication? _____

7: On a scale of 0-10 (10 being the most you would want to have the specific condition listed), how much would you like to have a surgery that has a 6.1% chance of a “severe” complication? _____

8: On a scale of 0-10 (10 being the most you would want to have the specific condition listed), how much would you like to have a surgery that has a 16.6% chance of a “severe” complication? _____

9: On a scale of 0-10 (10 being the most you would want to have the specific condition listed), how much would you like to have a surgery that has a 14.5% chance of a “secondary fusion” surgery? _____

10: On a scale of 0-10 (10 being the most you would want to have the specific condition listed), how much would you like to have a surgery that has a 100% chance of NOT NEEDING a “secondary fusion” surgery? _____

11: On a scale of 0-10 (10 being the most you would want to have the specific condition listed), how much would you like to have a surgery that has a 9.9% chance of needing to remove the operative hardware? _____

12: On a scale of 0-10 (10 being the most you would want to have the specific condition listed), how much would you like to have a surgery that has a 20.4% chance of needing to remove the operative hardware? _____

Figure 2. Questionnaire and brief introductory description completed by participants.

($3.91 \times 14.5\% = 0.57$), implant removal ($4.98 \times 16.3\% = 0.81$). When adding all the expected patient values ($5.6 + 1.07 + 0.67 + 0.24 + 0.57 + 0.81$), the overall expected value for ORIF is 8.96. This same calculation is repeated for ORIF+PSTA.

3.5. Sensitivity analysis

A one-way sensitivity analysis was performed, hypothetically decreasing the rate of secondary fusion following isolated ORIF and thereby increasing the overall expected value. Despite adjusting the rate of secondary fusion to 0%, the expected value of combined ORIF with PSTA still exceeded that of ORIF by nearly twofold (18.06 vs 9.45, respectively) (Fig. 3). Similarly, adjusting the moderate and severe complication rates following ORIF with PSTA to 100%, the expected value of ORIF with PSTA still exceeded that of ORIF (15.45 vs 8.96, and 13.52 vs 8.96, respectively) (Fig. 4).

4. Discussion

In this clinical investigation, we found hypothetical patients overwhelmingly preferred ORIF with PSTA over isolated ORIF

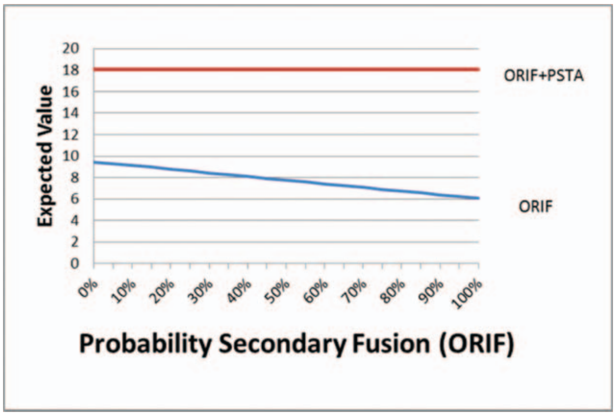

Figure 3. As the probability of secondary fusion with ORIF is artificially decreased to 0%, the expected value is still less than that for ORIF+PSTA.

for complex DIACFs. Patients furthermore preferred ORIF with PSTA for every individual utility with the exception of severe complications and implant removal (3.87 vs 2.9 and 4.98 vs 4.14, respectively), both of which had substantially greater frequency within the ORIF with PSTA cohort but which were very close in patient-assigned utility value to the ORIF cohort. The largest difference in utility value (8.72 vs 3.91) was evident for secondary arthrodesis, contributing most notably to the dramatically greater overall expected value for combined ORIF with PSTA. Patients therefore placed increased value on avoiding a secondary fusion procedure. Due to the nature of this decision analysis, it can only be speculated as to why patients placed such an increased value on avoiding a secondary surgery. The survey volunteers acting as hypothetical patients may feel that if there is a possibility of having a secondary surgery that "fixes" residual issues with the primary surgery, they may be receiving a suboptimal initial surgery. A possible critique of the questionnaire posing an option with a 100% rate of not needing a secondary fusion may influence the survey volunteers toward choosing this option due to its attractive rate; however, the survey is structured in such a way that patients are not asked to pick one option over the other, they are simply asked to pick how much they would like the presented option. Furthermore, the participants are unaware as to which probability is associated with a specific treatment option thus eliminating this bias. We also acknowledge that ORIF with PSTA does not have a 100% fusion rate; however, the articles were reviewed for the rate of secondary fusion and not union rates. Despite substantial differences in rates of moderate and severe complications, secondary fusion, and implant removal, the marked difference in assigned patient utilities and the overall expected values elucidates the optimal treatment based on patient preferences, which is not taken into account in most prior investigations evaluating either of the 2 treatments.[2,3,5,6,9]

Given the relative paucity of literature comparing ORIF to ORIF+PSTA, it is not surprising that there is no consensus for the optimal management of complex DIACFs. While some authors continue to advocate for conservative management, many contend that long-term functional outcomes have been shown to be superior following ORIF, with restoration of subtalar joint congruity and calcaneal height, width, and alignment.[2–8,16] Despite reported superior functional and clinical outcomes, operative management has been wrought with a relatively high rate of complications.[4,8,21,35] However, controversy arises when considering the option of concomitant subtalar arthrodesis at the time of index internal fixation.[5,36–39]

It has been suggested that the severity of the chondral injury to the subtalar joint in these high-energy fractures is often too severe to warrant isolated ORIF due to irreversible damage to intact portions of articular cartilage, chondral loss, and small fragment comminution, and that patients may fare better with concomitant PSTA.[3,9,22] An overwhelming number of patients progress to radiographic and clinical subtalar arthritis, often resulting in later arthrodesis; however, there remains no direct correlation between radiographic arthritis and manifestation of clinical symptoms.[6] When Sanders et al[5] studied the long-term outcome of types II and III calcaneus fractures, they found radiographic evidence of posterior facet osteoarthritis in 100% of patients, though not all patients went on to subtalar arthrodesis. Therefore, the difficulty arises in deciding whether or not to routinely arthrodese a joint that may ultimately not become symptomatic.

Previous studies have demonstrated that many patients who undergo isolated ORIF for DIACF may eventually go on to require subtalar arthrodesis.[3,5,9] While the range across published studies is broad (5%–47%), our review of the literature found a pooled probability that approximately 15% of DIACFs treated with isolated primary ORIF eventually required a secondary fusion.[3,5,9] Though ORIF+PSTA is a more extensive procedure and admittedly associated with loss of

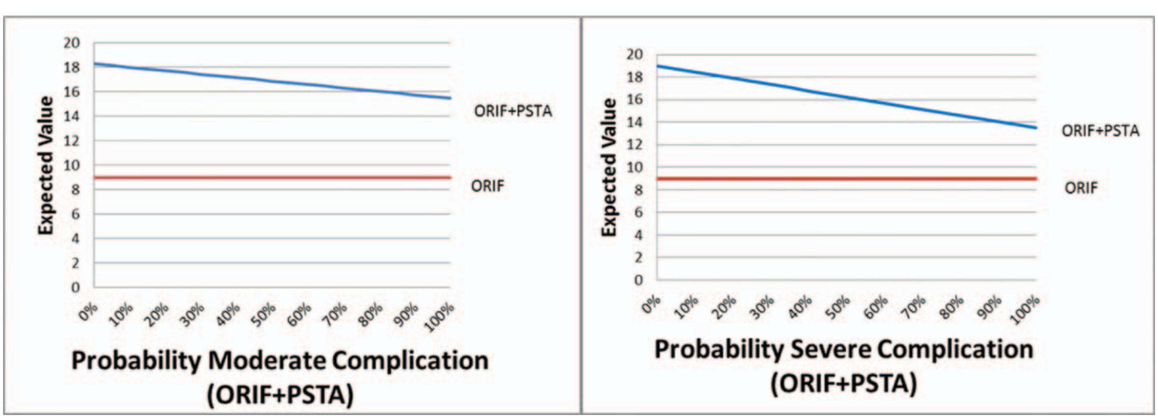

Figure 4. As the probability of moderate or severe complications is artificially elevated to 100% for ORIF+PSTA, the expected value still remains higher than ORIF.

hindfoot motion, an increased risk of neighboring joint arthrosis, and later implant removal, more recent studies have shown improved functional outcomes scores, when arthrodesis is performed in the acute versus delayed timeframe in patients initially treated with ORIF, and in patients treated with isolated ORIF.[6,9–14,23,24,40] While the only available randomized controlled trial comparing ORIF versus ORIF + PSTA, by Buckley et al,[9] did not demonstrate any statistically significant differences between the 2 treatment options, the authors do report improved mean SF-36 scores for ORIF + PSTA versus ORIF (38 vs 30). The interpretation is that while not reaching statistical significance, these results may be a trend and thus further investigation would be necessary to truly understand if a difference exists. This decision analysis model agrees with the trend that favors ORIF + PSTA over ORIF alone.

Given the superior pooled outcome probabilities and overall expected value for ORIF and PSTA, strong consideration should be given to this treatment option during the initial surgery. The surgeon must weigh the impact of loss of subtalar motion and potential contiguous joint osteoarthritis with the potentially inferior functional outcome of a salvage arthrodesis procedure. While each fracture pattern requires individual evaluation and consideration of multiple factors by the treating surgeon, this decision analysis provides guidance based on patient preferences for outcomes. The decision on how to treat these fractures relies on multiple patient, surgeon, social, and clinical factors. This study provides clinical value as the results are based on patient preferences for outcomes. For many validated scoring systems used in orthopaedic studies, patient satisfaction is a substantial factor. The merit of this decision analysis is that it enables a quantitative, patient-centered analysis of 2 treatments for which there is an exceedingly limited number of long-term or comparative investigations evaluating functional outcomes. Our expected value decision analysis favors ORIF with PSTA in the acute setting for complex DIACFs, most notably attributable to patient preference for fusing a joint which might not become symptomatic but thereby avoiding any possibility of a secondary fusion procedure with a foreseeably inferior functional outcome. Surprisingly, patients placed such weight in this outcome that even by increasing the rate of moderate or severe complications following ORIF + PSTA to 100% during the sensitivity analysis, the overall expected value of a combined procedure still exceeded that of ORIF alone.

Our analysis is perhaps most limited by the scarcity of the literature evaluating outcomes following ORIF with and without PSTA for an otherwise rare and devastating injury as series are often small and with limited follow-up. However, this adds to strengthen this decision analysis as an aid in deciding the optimal patient-centered treatment. An unavoidable limitation is the use of volunteers as hypothetical patients in that they may not fully understand the implications of the questions being asked. Patients were additionally not allowed to consult with an orthopaedic surgeon on the treatment options. Consequently, it is a limitation in the methodology of all decision analyses, and is not specific to our study. This condition is intentional and serves a dual purpose: to mitigate selection bias and to avoid surgeon bias based on the preferred treatment. Our analysis, due to the nature of its methodology, is also unable to account for other factors which may influence outcome such as associated injuries, surgeon experience, or patient comorbidities.

Furthermore, this decision analysis is based solely on a questionnaire answered by hypothetical patients with no formal medical training, experience, or guidance by an orthopaedic surgeon. A complication that a surgeon may consider to be important such as the risk of infection requiring subsequent debridement, and the consequences that a wound which fails to heal entails, may not be truly appreciated by the survey volunteers. The difference in the utility value placed by these hypothetical patients for the severe complication category of 3.87 versus 2.90 with probabilities of 6.1% and 16.6% for ORIF and ORIF with PSTA, respectively, would likely be much broader if a group of surgeons were asked to fill out the questionnaire. A surgeon with intimate knowledge and experience of what a 10% difference in the probability of a severe complication truly means, for example an infection requiring debridement and its possible sequela, would likely give a much higher utility value to the option with a 6.1% probability versus the option with a 16.6% probability, *and thus would increase the expected patient value, and ultimately the overall expected value for ORIF.* Inversely related and similar to biomechanical studies, which may find statistically significant difference with an implant's properties that may not translate into clinical practice, the hypothetical patients may not value a 10% difference in complication rates, yet this 10% difference may have a potent influence on a surgeon's decision to offer a specific treatment option.

Many other factors are likely not being fully evaluated when the survey volunteers are faced with a questionnaire based solely on numbers, such as the value of joint preservation and range of motion with ORIF compared to arthrodesis. Because we do not know what the individual volunteer values, whether it be maintenance of range of motion and joint preservation with possible chronic pain, or pain relief at the expense of motion and possibly fusing a joint which may or may not be symptomatic in the future, this decision analysis cannot replace appropriate patient/surgeon counseling. Each treatment option should be carefully weighed, and tailored specifically to the individual patient based on multiple factors to include comorbidities, lifestyle, occupational requirements, and physical demands. In this same manner, we grouped complications based on broad terms. Minor complications involved those that did not require further medical or surgical care, moderate complications required medical care, and severe complications required operative treatment. As mentioned above, without formal patient counseling and preoperative discussion, a complication considered in this paper to be minor or moderate, such as dysaesthesia and complex regional pain syndrome, or anticoagulation with its associated risks and complications for treatment of a deep venous thrombosis and pulmonary embolism, can be disabling to some patients. As this analysis cannot be all inclusive, we cannot overemphasize the need for appropriate counseling and individualized treatment.

In conclusion, our expected value decision analysis favors ORIF with PSTA as the optimal patient-oriented treatment decision for DIACFs. Even with unrealistic adjustments in probabilities of the outcomes of interest (reducing secondary fusion to 0% following ORIF and increasing moderate and severe complication rates independently to 100% following ORIF with PSTA), the degree to which the expected value of isolated ORIF was artificially inflated was still grossly inadequate and did not approach the patient expected value of ORIF with PSTA.

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