Complication Risk Stratification for Revision Surgery following Total Ankle Replacement

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Statement of Purpose

Utilizing modern publications regarding implants currently on the market in the US we aim to develop an updated and inclusive classification system which stratifies the risk TAR complications have on a patient needing to return to the operating room.

Literature Review

Previously proposed classifications of TAR complications by Glazebrook et al and Gadd et al have attempted to establish the incidence at which certain complications occur and the effect those complications can have on survival of the prosthesis [1,2]. Glazebrook identified nine primary complications associated with TAR, and constructed a classification system to predict survivorship. These complications were subsidence, aseptic loosening, intra-op bone fracture, wound healing problems, technical error, implant, non-union, post-op bone fracture, and deep infection. These main complications were then subdivided into broad groups with a projected risk that those complications placed on the survivorship of the implant.

Gadd et al attempted to validate the Glazebrook risk classification to their own patients but found discordence. Specifically, Gadd et al found that that the Glazebrook model did not reflect the incidence of complications nor the attributed TAR survivorship in their own patient population. Furthermore, Gadd et al proposed categorizing complications as high or low risk for failure of TAR rather than mild, moderate, and severe. Despite both of these efforts, many commonly encountered complications such as cyst formation, heterotopic ossification, and many other relevant complications were excluded from the previous classification systems. These complications all can have an effect on the survival of an implant but also on the patient's need to return to the operating room.

Methodology

A systematic review of studies on TARs from 2013-2018 was performed in patients 18 years or older who received either a unilateral or bilateral total ankle replacement for end stage ankle arthritis. 16 studies fit inclusion criteria and exclusion criteria involving 3,305 implants. To determine complication incidence, we calculated an adjusted complication rate, as described by Glazebrook[1]. This was the number of specific complications, divided by the sum of all cases for only those studies reporting the complication of interest (Table 1).

Inclusion Criteria: Studies with at least 20 patients, at least 12 months of follow-up data, utilization of implants available in the US and studies that included complications data.

Exclusion Criteria: Case reports, basic science articles and studies published in non-peer-reviewed journals.

Complication	Complication Incidence (%)	TAR Survivorship (%)
Intra-Op Fracture	5.5	95.2
Wound Complication	5	95.6
Subsidence	3	92.6
AVN	2.6	92.5
Aseptic Loosening	3	93.4
Cystic Changes	3.5	93.6
Any Component Implant Failure	2.4	90.4
Post-Op Fracture	3.1	95.7
Hypertrophic Bone Formation	10.6	92.4
Infection	1.9	94

Table 1. Adjusted complication incidence rate and associated TAR survivorship

Results

- 16 studies met selection criteria totaling 3,305 implants.
- Mean TAR survivorship for included studies was more than 95%.
- There were 432 total complications total (13.1% incidence rate).
- Highest incidence of complications were seen in hypertrophic bone formation and lowest incidence was seen in deep infection.
- Failure of any implant component was found to have the lowest TAR survivorship.
- Infection reporting in studies as well as classification of a deep and superficial infection did not show consistency in criteria between the reviewed studies. To attempt to control for this we combined the incidence of deep and superficial infections in the final analysis.
- Table 2 demonstrates the incidence of TAR outcomes and the associated survivorship for the reporting studies.
- Applying the Glazebrook risk classification on the current dataset, high risk complications would yield a 92.3% survivorship, while the medium and low risk categories yielded survivorship rates of 93.7% and 95.9% respectively. Gadd's proposed modification combined the medium and high risk groups together and when applied to the current dataset, the survival rate remained 95.9% for the low risk complications, and only modestly increased to 92.9% in the combined high risk category.
- Table 3 shows our update to the classification of complications based on the data from the current systematic review. Complications are separated into low, medium and high complications based on associated TAR survivorship.

Outcomes	Incidence (%)	TAR Survivorship (%)
Poly Exchange	5.5	95.2
TAR Implant Revision	5	95.6
BKA	2	90.6
Flap	1.2	94
Any Fusion	3	92.6
- TTC Fusion	2.6	92.5
- AJ Fusion	3	93.4

Table 2. Outcome incidence and associated TAR survivorship

- Outcome data showed that returning to the OR for additional procedures can also effect the survivorship of the the Implant even if the implant is not directly involved in the secondary case.

Image 1. Wound complication following TAR.

Analysis & Discussion

Relative Risk

- High Risk Complications (Any component implant failure, AVN, Subsidence) had a relative risk of implant failure that was 61% higher than low risk complications.
- High Risk Complications (Any component implant failure, AVN, Subsidence) had a relative risk of implant failure that was 20% higher than medium risk complications.
- Medium Risk Complications (Infection, Aseptic loosening, Cystic changes) had a relative risk of implant failure that was 34% higher than low risk complications.

- In Figure 1 one can see the comparison between the incidence of complications found in Glazebrook et al, Gadd et al, and the present study. There are obvious substantial fluctuations between studies regarding the incidence of complications which speaks to the . Technical error and nonunion were excluded from comparison because there was lack of criteria consistenecy for reporting such outcomes.
- Hypertrophic bone formation is a complication that is unclassifiable by previous classifications yet our review shows that the associated survivorship of an implant with this complication is similar to that of AVN or aseptic loosening.
- In studies reporting wound complications such as seen in Figure 1 that needed flap closure, there was no association with lower implant survivorship.

Complication	Incidence (%)	TAR Survivorship (%)
High Risk		92
Any Component Failure	2.4	90.4
AVN	2.6	92.5
Subsidence	3	92.6
Medium Risk		94.1
Aspetic Loosening	3	93.4
Cystic Changes	3.5	93.6
Infection	1.9	94
Low Risk		95.6
Intra-Op Fracture	5.5	95.2
Wound Complications	5	95.6
Post-Op Fracture	3.1	95.7

Table 3. Updated complication classification system based on TAR survivorship associated with specific complications

Conclusion

Through our review of recent TAR literature we found that there is a lack of consistency in criteria for reporting and evaluating complications. A major consideration is that more recent studies show a far higher average survivorship than those reported in the Glazebrook study. As technology improves the impact of these complications have become less catastrophic. To achieve a more accurate understanding of complications and their effect on TAR survivorship, authors must elaborate on the complications they encounter with TAR. Our proposed classification system provides an updated and inclusive classification system that captures more complications that can occur after TAR. Further, this system provides a stratification of risk that these complications pose to the survivorship of the implant and the need for a patient going back to the operating room.

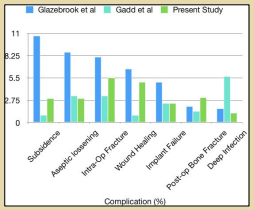

Figure 1. Comparison of complication incidence between previously published studies and the present study.

References

1. Glazebrook M, Daniels T, Younger A, Foote CJ, Penner M, Wing K, Lau J, Leighton R, Dunbar M. Comparison of health- related quality of life between patients with end-stage ankle and hip arthrosis. J Bone Joint Surg Am. 90(3):499–505, 2008.
2. Gadd RJ, Barwick TW, Paling E, Davies M, Blundell C. Assessment of a Three-Grade Classification of Complications in Total Ankle Replacement. Foot Ankle Int. 35(5), 434-437, 2014.
3. Jastifer J, Coughlin MJ, Hirose C. Performance of Total Ankle Arthroplasty and Ankle Arthrodesis on Uneven Surfaces, Stairs, and Inclines: A Prospective Study. Foot Ankle Int. 36(1):11-17. 2015.
4. Demetracopoulos CA, Adams SB, Queen RM, DeOrio JK, Nunley JA, Easley ME. Effects of Age on Outcomes in Total Ankle Arthroplasty. Foot Ankle Int. 36(8):871-880. 2015.
5. Gross CE, Hamid KS, Green C, Easley ME, DeOrio JK, Nunley, JA. Operative Wound Complicatons Following Total Ankle Arthroplasty. Foot Ankle Int. 38(4):360-366. 2017.
6. Harston A, Lazarides AL, Adams SB, DeOrio JK, Easley ME, Nunley JA. Midterm Outcomes of a Fixed-bearing total ankle arthroplasty with deformity analysis. Foot Ankle Int. 38(2):1295-1300. 2017
7. Queen RM, Sparling TI, Butler RJ, Adams SB, DeOrio JK, Easley ME, Nunley JA. Patient-reported outcomes, function, and gait mechanics after fixed and mobile-bearing total ankle replacement. J Bone Joint Surg. 96:987-993. 2014.
8. Stewart MO, Green CL, Adams SB, DeOrio JK, Easley ME, Nunley JA. Midter results of the Salto Talaris total ankle arthroplasty. Foot Ankle Int. 38(11):1215-1221. 2017.
9. Lewis JS, Adams SB, Queen RM, DeOrio JK, Nunley JA, Easley ME. Outcomes after total ankle replacement in association with ipsilateral hindfoot arthrodesis. Foot Ankle Int. 35(6):535-542. 2014.
10. Lewis JS, Green CL, Adams SB, Easley ME, DeOrio JK, Nunley JA. Comparison of first- and second-generation fixed-bearing total ankle arthroplasty using a modular intramedullary tibial component. Foot Ankle Int. 36(8):881-890. 2015.
11. Gaudot F, Colombier JA, Bonnin M, Judet T. A Controlled, Comparative Study of Fixed-Bearing versus Mobile-Bearing Ankle Arthroplasty. Foot Ankle Int. 35(2):131-140, 2014.
12. Palanca A, Mann RA, Mann JA, Haskell A. Scandinavian Total Ankle Replacement: 15 year follow-up. Foot Ankle Int. 39 (2):135-142. 2017.
13. Lampley A, Gross CE, Green CL, DeOrio JK, Easley M, Adams S, Nunley JA. Association of Cigarette Use and Complication Rates and Outcomes Following Total Ankle Arthroplasty. Foot Ankle Int. 37(10):1052-1059. 2016.
14. Flavin R, Coleman SC, Tenenbaum S, Bodsky JW. Comparison of Gait after Total Ankle Arthroplasty and Ankle Arthrodesis. Foot Ankle Int. 35(5):434-437. 2014.
15. Sung KS, Ahn J, Lee KH, Chun TH. Short-term Results of Total Ankle Arthroplasty for End-stage Ankle Arthritis with Severe Varus Deformity. Foot Ankle Int.
16. Bouchard M, Amin A, Pinsker E, Khan R, Deda E, Daniels TR. The Impact of Obesity on the Outcome of Total Ankle Replacement. J Bone Joint Surg. 97:904-10, 2015.
17. Johnson-Lynn SE, Ramasakandhan J, Siddique MS. The effects of patient age and diagnosis on the 5-year outcomes of mobile-bearing total ankle replacement. The Foot.36:1-5.2018.