August 16, 2022

Do Generic Volar Locking Plates Provide Similar Outcomes at a Reduced Cost?

Study Protocol and Statistical Analysis Plan

Study Narrative

1. *Summary*

Distal radius fractures are a common injury in the community. When treated with open reduction internal fixation (ORIF), the volar locking plate (VLP) is the most frequent implant used. Current literature has shown most orthopaedic surgeons are unfamiliar with construct costs. Many surgeons use implants the hospital provides and have no preference for one implant company's plate over another. Previous studies have demonstrated increased implant costs do not increase patient reported outcomes (PROs) in other injury patterns. Generic implants can potentially reduce total procedural costs and not negatively impact patient outcomes. With an increasing emphasis being placed on providing high-value care to patients, and rising healthcare costs, there is a need to pursue more economical means of treating distal radius fractures. Additionally, with the increasing volume of distal radius fractures with a growing elderly population, it is important to consider adoption of an already partially implemented process. Some surgeons today in our health system use the generic VLP, with little apparent differences in reoperation rates and complications. Validation of its safety and efficacy on a larger scale could support its adoption as a universal stand of practice, thus reducing cost to the patient and hospital.

2. *Study aims:*
   - *a.* Primary:
     - *i.* To determine if there is any difference in 90-day reoperation rate between patients treated with a generic or conventional volar locking plate.
     - *ii.* To determine if there is any difference in 90-day readmission rate between patients treated with a generic or conventional volar locking plate.
     - *iii.* To determine if there is any difference in 90-day mortality rate between patients treated with a generic or conventional volar locking plate.

   - *b.* Secondary:
     - *i.* To determine if generic implants have a lower cost than conventional implants.
     - *ii.* To determine any differences in estimated blood loss by implant type (generic vs. conventional).
     - *iii.* To determine tourniquet time by implant type (generic vs. conventional).

3. *Background, Rationale, Significance*

   a. Healthcare costs continue to rise in the United States, while Medicare reimbursement rates are declining (Haglin JOT 2021). With that, orthopaedic surgery is becoming a common target of cost containment strategies as musculoskeletal related procedures account for approximately one-quarter of surgical procedures performed in the United States (Seltzer JOT 2023). In addition, Medicare reimburses for roughly one-third of all orthopaedic procedures (Payne Am J Orthop 2015). One of the largest contributors to the overall cost of orthopaedic procedures is implant cost. On average implants attribute to 43-50% of procedure costs, and in some cases up to 87% of costs (Robinson JBJS 2012). Implant selection is also largely influenced by surgeons, although many are not aware of implant cost (Streit, Okike). With implants accounting for a large

proportion of overall cost, and being heavily determined by surgeons, implant-related cost reduction strategies such as using generic implants are critical to lowering costs in orthopaedic surgery.

Generic implant use has been shown to generate an average cost-savings of 49%, and in some cases up to 73% in orthopaedic trauma procedures (Kleinsmith COP 2024). Despite the reduction in cost related to generic implant use, it appears that there is still some concern among surgeons and patients over their quality and safety. One survey reported that 52% of the public see the value of generic implants, however only 26% would want them used in their surgery (Miner Ach Bone Surg 2022). Regarding surgeons, an OTA member survey found that many are aware of generic implants (73%), but only 26% use them in practice (Althausen 2016 JOT). Prior literature has compared generic cephalomedullary nails (CMNs) to brand name CMNs and found no difference in 6-month clinical and radiographic outcomes (Khoo JAAOS 2022, Kleinsmith 2024). Although this has been demonstrated in other injury patterns, there is a paucity of literature surrounding differences in cost and clinical outcomes associated with generic implant use in distal radius fracture (DRF) open reduction and internal fixation (ORIF).

DRFs are a prime target for generic implant implementation, due to the relatively high incidence of DRFs (634,000 annually) (Mauk Orthop Clin North America 2018), and the substantial amount spent by Medicare each year on DRF management ($385-$535 million) (Ray JBMR 1997, Burge JBMR 2007). The purpose of this study was to assess for differences in implant cost, surgical characteristics, and 90-day clinical outcomes between patients treated with generic volar locking plates (VLPs) and conventional VLPs in the setting of a DRF. We hypothesized that there would be no difference in surgical characteristics (e.g., tourniquet times) or clinical outcomes (e.g., reoperation), however there would be reduced cost in the generic VLP group.

4. *Approach*
    a. Study design
        i. This will be a prospective randomized controlled trial within Healthpartners in the greater Minneapolis area in Minnesota, to compare primary outcomes of subjects between generic and conventional volar locking plates in distal radius fracture patients. Group selection will be randomized month to month with generic plates being used one month and conventional plates the next.

        i. Inclusion
            1. >18 years old
            2. Isolated DRF
            3. Medical need for surgical fixation with a volar locking plate
        ii. Exclusion
            1. No VLP used
            2. Additional fixation used
            3. Injury was non-isolated (polytrauma)
            4. < 18 years old
            5. Open fracture

b. Data collection process
    i. Identify patients within HealthPartners who meet inclusion criteria who are determined to need distal radius ORIF
        1. Patients meeting inclusion criteria will be identified by the included surgeons on the study
    ii. Consent
        1. Written informed consent for surgery will be obtained by the attending surgeon, however no additional consent will be needed as this is an FDA approved device
    iii. Data sources needed for this study
        1. Chart Review for patient age, gender, height and weight
        2. Chart review for mortality, reoperation, readmission
        3. Chart review for implants, tourniquet time, estimated blood loss
        4. Implants will be cross referenced with institutional charge master database to obtain cost.
    iv. Process steps for data acquisition
        1. Data to be obtained by chart review after completion of the study.
c. Intervention, treatments
    i. Patients will be randomized by month with patients during one month receiving generic implants and the following month they receive conventional implants.
    ii. All other standards of care remain equal between the groups.

d. Outcomes/endpoint and other variable definitions, and instruments used
    i. 90-day reoperation
    ii. 90-day readmission
    iii. 90-day mortality
    iv. Implant cost
    v. Estimated blood loss
    vi. Tourniquet Time

e. Statistical analysis plan
    i. T-Tests and Chi-square of Demographic Data
    ii. Chi-square of primary outcomes
        1. 90-day reoperation rate
        2. 90-day readmission rate
        3. 90-day mortality rate
    iii. T-Test of Secondary Outcome Measures between subject groups
        1. Implant cost
        2. Tourniquet time
        3. Estimated blood loss
    iv. Power analysis or statement of precision
    An a priori power analysis was conducted to estimate the minimum sample size needed to adequately detect a difference in reoperation rates with a large effect size (Cohen's d=0.8). At a Type I error rate of 0.05, a power of 80%, and a 1:1

group allocation, the estimated sample size was 36 patients (18 generic VLPs vs. 18 conventional VLPs).

v. Strengths

1. Blinding of patients
2. Use of FDA approved devices
3. Randomizing of patients
4. Adequate qualified staff members to conduct the study
5. Surgeons will be adequately trained and reminded on the protocol and their specific research related duties.
6. High-volume surgeons who regularly treat distal radius fractures
7. Conservative effect size estimates

vi. Limitations

1. Surgeons are not blinded
2. Only early follow-up (90 days)
3. No patient reported outcomes included

5. Setting/Environment/Organizational feasibility
    a. This study will be conducted at Healthpartners within Minneapolis metropolitan area
    b. This HealthPartners setting has an appropriate patient population to carry out the proposed study.
    c. The orthopedic department leadership has been engaged in development and approval of this study
6. Risks and Benefits
    a. Potential risks
        i. No different than associated risks of undergoing a standard DRF ORIF.
    b. Benefit to society
        i. Being able to validate the use of cheaper implants to save cost for patients and healthcare systems.
7. Data Confidentiality and Privacy
    a. In order to secure patient confidentiality and data security, all data will be de-identified. All patients will be assigned a research identification number (not their MRN) that cannot be associated with their name, birthdate, or other identifying information.
    b. Patient information will only be accessed via secure servers for TRIA and on encrypted password-protected computers. If it is necessary to transmit patient data, it will be transmitted in the de-identified format, using only patient research identification numbers.
    c. At the end of the study, the electronic files will be permanently deleted and patient identifiers will be removed.

8. Timeline
    a. August 2022: IRB submission
    b. September 2022: IRB approval
    c. October 2022: Protocol implementation
    d. April 2023: Patient enrollment closes
    e. May 2023: Data analysis
    f. July 2023: Manuscript preparation

g. July 2023: Manuscript submission

9. Dissemination/Sharing Results/Integration and Impact
    a. We do plan on publishing to peer reviewed orthopedic journals such as;
        i. The Journal of Bone and Joint Surgery
        ii. Clinical Orthopedics and Related Research
        iii. Journal of Orthopedic Trauma
    b. We plan to disseminate the information on a local and regional level by presenting at;
        i. University of Minnesota Grand Round
        ii. Minnesota Orthopedic Society poster presentation
        iii. Mid-America Orthopedic Society poster presentation
    c. Results will be shared with HealthPartners