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## Statement of Purpose

Ulcerations are a frequent antecedent of elective lower extremity amputations in patients with diabetes related neuropathy. Hallux ulcerations develop from increased plantar pressures through a combination of non-reducible pedal deformities, flexor hallucis longus contractures, and neuropathy (1). Traditionally, neuropathic ulcerations are treated non-operatively combining offloading techniques and local wound care. Operative intervention consists of prominent bone and joint resection that contribute to increased pressure and ulcer formation. The authors present a retrospective study evaluating the efficacy of hallux interphalangeal joint (HIPJ) arthroplasty to address recalcitrant hallux ulcerations.

## Methodology & Hypothesis

A 5 year retrospective review comparing HIPJ arthroplasty with non-operative treatment of recalcitrant plantar hallux ulcerations was performed. Patients were treated between January 2008 and May 2013 at the Cleveland Clinic, Cleveland, OH. This investigation was conducted with Institutional Review Board approval. Patients with chronic plantar or plantar-medial ulcerations were identified utilizing an electronic medical record database. Each case was reviewed by two investigators (EL and NN). The authors hypothesize patients who undergo HIPJ arthroplasty yield favorable outcomes in the immediate and long-term periods.

### Inclusion Criteria:

- Patients with diabetic neuropathy or idiopathic peripheral neuropathy, and
- Plantar hallux ulcerations present for longer than 6 weeks

### Exclusion Criteria:

- Prior hallux surgery
- Ulcer duration for less than 6 weeks
- Ulcerations not located on the plantar or plantar medial surface of the hallux
- Patients with incomplete documentation or lost to follow-up

Patients were placed into one of two treatment groups:

- HIPJ arthroplasty
- Control group of various offloading techniques

### Outcomes explored:

- The number of weeks until ulcer healing after initiation of treatment
- Ulceration recurrence
- Amputations
- Other variables for an association with non-healing and patient co-morbidities.

### Also Correlated:

- Demographics: age, gender, and body mass index (BMI)
- Ulcer: duration (weeks) and size prior to treatment (cm<sup>3</sup>) (Figure 1a)
- Co-morbidities: diabetes mellitus (DM), chronic kidney disease (CKD), peripheral arterial disease (PAD), hemoglobin A1C, and tobacco use.
- Surgical complications: Incidence of infection, dehiscence, neuritis, new ulceration site, and deep vein thrombosis

### Statistical Analysis

Continuous variables were described by means and standard deviations, or medians and interquartile ranges. Both ordinal and nominal categorical variables were described using counts and percentages. Differences in continuous variables between surgical and conservative treatment groups were tested using either the paired t-test or paired Wilcoxon's signed rank test. Differences in nominal categorical variables were tested using the exact McNemar test. Differences in ordinal categorical variables were tested using paired Wilcoxon's signed rank test. Time to heal was analyzed using Cox's proportional hazard models with clusters defined by the matched group number, with the comparison between groups based on a Wald test. Median healing times were estimated using the Kaplan-Meier method. All analyses were performed using R Software (version 3.0.1, Vienna, Austria). A 5% level of significance was used for all testing.

## Procedure

Patients in group 1 underwent HIPJ arthroplasty (Fig.1a). A standard procedure was performed through a dorsal approach over the HIPJ (Fig. 1b). Dissection was carried through subcutaneous tissue where the extensor hallucis longus (EHL) was identified and retracted. When necessary for exposure, the EHL was transected and later repaired. The HIPJ was exposed and the head of the proximal phalanx was removed with a saw blade. In some cases, fixation with a 0.062 K-wire was placed percutaneously for stabilization of the hallux during the healing period. Skin was closed with non-absorbable suture in simple interrupted fashion. Post operative course consisted of protected weight bearing and fore-foot offloading. All patients in group 2 received standard offloading techniques with either total contact casting, custom molded inserts, or forefoot relief shoes (Figure 3). All patients received appropriate wound debridement and local wound care throughout the treatment periods.

Figure 1. Procedure



a) A 50 year old diabetic male with a chronic neuropathic plantar hallux ulceration. b) HIPJ arthroplasty was performed through a dorsal approach. c) 8 weeks postop demonstrating complete healing of the plantar ulceration.

Figure 2. Range of Motion



a) Pre-operative range of motion of the hallux interphalangeal joint. b) Increased post-operative range of motion of the hallux interphalangeal joint.

## Literature Review

To the authors' knowledge, only one study has evaluated the efficacy of HIPJ arthroplasty for the treatment of recalcitrant hallux ulceration (2). In 1994, Rosenblum reviewed 46 HIPJ arthroplasties on 40 patients for chronic neuropathic ulcers of the hallux. He found that 91% of patients had healed with no evidence of recurrence in the follow-up period, which ranged from 4 to 44 months. This study concluded that HIPJ arthroplasty is a valuable procedure for chronic ulcerations. There have been several proposed surgical treatments for healing of digital ulcerations including metatarsal head resection, arthrodesis, and amputation (3).

## Literature Review

A study by Armstrong et al. in 2003 concluded that a first proximal phalangeal base resection, or Keller osteotomy, resulted in faster healing time and fewer re-ulcerations than the standard conservative therapy group (4). One study by Stephens et al. in 2000 described how an FHL contracture release could be used to reduce plantar pressure and heal chronic plantar hallux ulcerations (1). Kim et al. in 2008 revealed that removal of a lesser digit phalanx can result in ulceration healing (5). Quebedeaux et al in 1996 concluded that hallux amputation contributes to lesser digital deformities and new ulcer formation (6). Lavery et al. 1996 postulates this is because after a hallux amputation, pedal pressure distribution is altered and increases re-amputation risk (7).

## Results

A total of 158 patients with chronic plantar hallux ulcerations were treated between January 2008 and May 2013 within the Podiatric Centers at the Cleveland Clinic. 55 patients met inclusion criteria for review after applying exclusion criteria. 13 cases of HIPJ arthroplasty were allocated to group 1 (surgical). The remaining 42 were placed into group 2 (control). Furthermore, 13 age-matched patients were selected from group 2 to comprise the final comparison control group. See Table 1 for comparison of patient characteristics. Average age was 55 years ± 13.0 years. Patients were 73% men. Average follow-up was 19.5 weeks with a range of 5 to 208 weeks. Median healing time was found to be 9 weeks in the control group and 3.5 weeks in the surgical group (p= 0.033). Ulcer recurrence rate was 1/13 (8%) in the surgical group and 7/13 (54%) in the control group (p=0.041). Amputation rate was 0/13 in the surgical group and 5/13 (38%) in the control group (p=0.063). Table 2 shows comparisons of healing time, recurrences, and amputations between the two groups.

Table 1. Comparison Characteristics of Patients

Factor	Surgical Group N = 13 (%)	Control Group N = 13 (%)	p value
Patient Age <sup>a</sup>	55.38 ± 13.02	54.77 ± 12.28	0.87 <sup>T</sup>
Gender	5 F/ 8 M	2 F/ 11 M	0.38 <sup>M</sup>
BMI (>25.0)	12(92.3)	12(92.3)	n/a
Diabetes Mellitus Neuropathy	13(100)	13(100)	n/a
Chronic Kidney Disease	4(30.77)	7(43.85)	0.45 <sup>M</sup>
Peripheral Arterial Disease	1(7.69)	4(30.77)	0.13 <sup>M</sup>
HgA1C (>6.5%)	16 (51.6)	11 (84.6)	0.81 <sup>W</sup>
History of Tobacco Use	8(72.7)	4(36.36)	0.25 <sup>M</sup>
Osteomyelitis	1(7.69)	1(7.69)	>0.99 <sup>M</sup>
Ulcer Volume (>1.0 cm <sup>3</sup> )	13(100)	13(100)	>0.99 <sup>W</sup>
Ulcer Duration (>6 weeks)	13(100)	13(100)	0.001 <sup>W</sup>

Table 1 lists the baseline characteristics of the surgical group compared to the age-matched control group. <sup>T</sup> Paired t-test, <sup>M</sup> Exact McNemar's test, <sup>a</sup> Mean + SD, <sup>W</sup> Wilcoxon's signed rank test

Table 2. Comparison of Outcomes Between Groups

Factor	Surgical Group N = 13 (%)	Control Group n=13 (%)	P Value
Time to Heal (in weeks) <sup>b</sup>	3.5 [2.5, 4.25]	9 [2, 17.29]	0.033 <sup>H</sup>
Recurrence <sup>a</sup>	1 (7.69)	7(53.85)	0.031 <sup>M</sup>
Amputation <sup>a</sup>	0(0)	5(38.46)	0.063 <sup>M</sup>

Table 2 shows comparisons of healing time, recurrences, amputations between the surgical and control groups. Statistical significance was found for shorter healing time and less recurrence in the surgical group. <sup>a</sup> Percentage, <sup>b</sup> Sample median, <sup>M</sup> Exact McNemar test, <sup>H</sup> Wald test from Cox

## Analysis and Discussion

Figure 3. Preventive Offloading



a) Drill-and-fill shoe with offloading insert

Results of this study reveal HIPJ arthroplasty is effective in addressing chronic plantar hallux ulcerations in diabetic patients with neuropathy. Our results correlate with Rosenblum's study performed over 20 years ago. The concept of internal offloading of chronic ulcerations has been described and applied to other areas of the foot (8). Osseous prominence of the HIPJ along with plantar contractures and restricted motion predisposes the plantar aspect of the hallux to ulcer formation in neuropathic patients. Resection of this joint prominence internally relieves pressure on the soft tissue eliminating one key factor in ulcer development and recurrence.

In the surgical group, ulcerations healed over a shorter period with no amputations occurring post-operatively. All patients used custom inserts and protective footwear after ulcers healed, which played a key role in preventing ulcer recurrence (Fig. 3). One ulcer recurrence was observed in this group at 2 years post-operatively. Further evaluation of this patient revealed co-morbidities characteristic of advanced disease. In addition to a diagnosis of DM, CKD, and PAD, patient exhibited a HgA1c > 10%, an ABI >1.3 and ulcer volume > 5 cm<sup>3</sup>. This patient also took the longest to heal postoperatively (12 weeks). Given these findings, we expect that patients with vasculopathy, long-standing disease, uncontrolled blood glucose, and larger ulcers to have poorer outcomes. Other observed outcomes observed include ulcer development to lesser rays. We identified new ulcers that formed to the 2<sup>nd</sup> toe in 2 patients and to the plantar 2<sup>nd</sup> metatarsal phalangeal joint in 1 patient. These healed uneventfully without surgical intervention. HIPJ arthroplasty may render the hallux unstable and shortened if there is excessive resection of the proximal phalangeal head. Thus, potential sequelae of this procedure are transfer lesions to the 2<sup>nd</sup> ray. The surgeon will need to determine how much bone resection is necessary, while taking into account 2<sup>nd</sup> digit length, to avoid transfer lesions, ulcer recurrence, hallux instability, and excessive shortening. Additional fixation with a 0.062 K-wire was not used in the presence of deeper ulceration or suspicion of infection.

Limitations of this study include the retrospective nature which consequently was found to have incomplete or missing records. Also the number of patients in both treatment groups was small, limiting stronger statistical analysis measures pertaining to time-to-event outcomes. There is also the possibility of selection bias relating to patient compliance in the surgical group. More advanced, higher-powered, prospective or randomized control trials are necessary to further evaluate this procedure as a curative measure for chronic plantar hallux wounds.

In conclusion, HIPJ arthroplasty for the treatment of recalcitrant hallux ulcerations yields favorable outcomes in the immediate and long-term periods including shorter healing time. This procedure is a viable option for the foot and ankle surgeon in preventing hallux ulcer recurrence and amputations in patients with diabetes related neuropathy.

## References

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