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# The effect of needle tenotomy on hammer, mallet and claw toe deformities in patients with diabetes, a retrospective study



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# ABSTRACT

*Aim:* The aim of this study was to evaluate outcomes of needle tenotomies as a treatment option for hammer, mallet and claw toes in patients with diabetes.

*Methods*: This was a retrospective study where all patients receiving flexor tendon tenotomy by needle at our outpatient clinic were identified through the electronic patient record system.

*Results:* A total of 81 patients that had 106 tenotomy procedures performed were identified. The 81 included (68% male) had an average age of 65.4 years, and 27 (33%) had Type 1 diabetes. Of the 106 procedures 36 were performed due to an ulcer on the feet. Of the 36 treated ulcers, 34 (94%) healed in an average time of 28 days. Tenotomies performed to prevent impending ulcers from progressing to active ulcers, were performed 84 times in total. Of the 84 procedures 6 patients progressed to an active ulcer. No serious complications i.e. infections or amputations in relation to the procedure were registered.

*Conclusion:* Needle flexor tenotomies are a relatively safe and effective treatment compared to tenotomies done by scalpel, both as treatment for ulcers and to prevent formation of new ulcers associated with hammer, mallet and claw toe deformities. As a side note, transfer lesions are avoidable if all toes on one or both feet are tenotomized in one procedure.

# Introduction

Diabetes is one of the largest health challenges facing the world, with around 422 million people affected globally in 2014, causing an estimated 1.5 million deaths worldwide annually [1]. One of the most severe complications to diabetes is foot ulcers, with an annual incidence of new ulcers between one and four percent, a prevalence of four to ten percent and a lifetime incidence of up to twenty five percent for patients with diabetes, depending on confounding factors and comorbidities [2]. Diabetic foot ulcers are associated with increased mortality, comparable to common cancer types and have been associated with a higher mortality than has been observed for macrovascular disease [3]. Diabetic foot ulcers are strongly associated with lower extremity amputations, with an estimated 85% of lower extremity amputations preceded by a diabetic foot ulcer [4].

One of the largest risk factors for diabetic foot ulcers is foot deformities with hammer, mallet and claw toes being some of the most common foot deformities and risk factors of diabetic foot ulcers [5–7]. The etiology of hammer, mallet and claw toe deformities in patients with diabetes is controversial and not well understood. Several theories have been proposed, but the most prevalent theory states that neuropathy driven atrophy of the intrinsic muscles leads to an imbalance between intrinsic and extrinsic musculature, leading to the three deformities [8].

The first line of treatment to prevent foot ulcers in patients with diabetes and foot deformities is offloading therapy in the form of devices e.g. shoes, casts, boots etc. The scientific evidence to support offloading therapy is still lacking, and the role of offloading therapy is controversial [9]. In clinical practice however, offloading is still essential in the prevention as well as treatment of diabetic foot ulcers. In some cases, offloading therapy alone is not enough and offloading surgery e.g. flexor tenotomies can be considered necessary. When treating patients with diabetes and hammer, mallet and claw toe deformities, flexor tenotomies have been a treatment option for many years. Several studies have shown promising effects of tenotomies

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performed with a scalpel on wound healing and prevention of new ulcers, including a study from our institute [10], but all studies have been smaller with a retrospective case design [11,12].

In 2015, we decided to convert from doing tenotomies by scalpel to performing the operation with a needle. This change was mainly driven by a wish to minimize size of incision, and to simplify the procedure, as needle tenotomies require a smaller setup than tenotomies done by scalpel. No data has been published on tenotomies done by needle when treating hammer, mallet and claw toes. However, several studies have been published on needle tenotomies performed on other indications e.g. talipes equino varus (clubfoot) in children, as a treatment of tendon contractures of patients with cerebral palsy and finger contractures of the institutionalized elderly patients [13–15].

It has been estimated that the cost of a diabetic foot ulcer is US \$17,519, the cost of a below ankle amputation is US\$43,800 and of an above ankle amputation US\$66,215 [16]. Thus, preventing ulcers or making them heal faster is of utmost importance for patients with diabetes and for the society.

The aim of our study was to assess outcome of tenotomy performed by needle. We presumed that performing the procedure with a needle rather than a scalpel would be safe, less invasive, leaving a smaller incision, and thereby had less risk of infection and dehiscence of the incision and did not anticipate serious adverse effects.

The study will be the first evaluating needle tenotomies, and at the same time the largest study looking at the outcomes of tenotomies.

# **Material and Methods**

This study was performed as a retrospective case study approved by the Danish Patient Safety Authority. All patients with diabetes and hammer, mallet and claw toe deformities who had flexor tenotomy performed with needle, between April 1st, 2015 and April 30th, 2017, at Steno Diabetes Center Copenhagen, were identified through electronic patient records by procedure code KNHL39 (myotomy or other tenotomy in ankle/foot) according to the ICD-10 code system.

All patients had either ulcers or impending ulcers associated with the deformities in the form of tip of the toe ulcers placed on pulpa of the affected toe, "kissing" ulcers placed between the affected and a neighboring toe, dorsal ulcer placed on the dorsal aspect of the proximal Vibration threshold was measured by biothesiometry in volts (V) using a biothesiometer (Bio Medical Instrument Co, Ohio, USA) on the tip of the first toe on both feet in a quiet and relaxed setting, with patients' eyes closed and after instruction of the patient to inform when they felt a tingling sensation. The procedure is repeated twice, and the average of the two tests is noted. The participants were grouped according to a vibration threshold of > 25 V and > 50 V.

Participants were also tested with monofilament [21,22]. Monofilament test was performed with a 10-gram Siemens Weinstein test. The monofilament was applied to three points; tip of the first toe, plantar to head of the first and fifth metatarsal. Patients were sitting in a relaxed and quiet setting, with eyes closed, and instructed to inform when they felt touch of monofilament. Monofilament test was positive if the participant did not register the monofilament on two or more of the three test points on foot.

Ulcer diagnosis was categorized into neuropathic, ischemic and neuro-ischemic according to the result of biothesiometry, palpable pedal pulses and distal blood pressure measurement of the foot. Neuropathic ulcers were defined as ulcers of patients with vibration threshold > 25 V and a palpable foot pulse, neuroischemic ulcers as ulcers of patients with vibration threshold > 25 V, toe pressure of 40–70 mmHg and/or ankle brachial index < 90%, ankle pressure > 75 mmHg, and ischemic ulcers as ulcers of patients with toe pressure < 40 mmHg and/or ankle pressure < 75 mmHg [19].

Tenotomies were performed in our outpatient foot clinic with the patient sitting with elevated feet. Planned incision sites were cleaned with a colored 0.5% chlorhexidine solution twice. After sufficient local anesthetics with 1% lidocaine was administered subcutaneously, the procedure was performed using a 40 mm long and 1.2 mm in diameter needle (BD Microlance<sup>™</sup> 3, produced by Becton, Dickinson and Company, New Jersey, USA). The needle was introduced through the plantar aspect of the foot, in a location corresponding to the presumed placement of the tendon(s) that was planned for tenotomy. All toes planned for tenotomy were anesthetized and tenotomized through separate portals. After introduction of the needle through the skin, flexor tendons were severed, a dry gauze bandage was applied and secured with an elastic bandage. The patient was placed with foot/feet elevated for 30 min in the waiting area to ensure hemostasis. Bandages were inspected for bleeding before discharge. All patients were offered therapeutic sandals with rocker bottom after the procedure (LINK TO VIDEO "Tenotomy Technique").



Tenotomy Technique.

interphalangeal joint of the affected toe or metatarsal head ulcer placed plantar to the metatarsal head of the affected toe [17].

Diabetic foot ulcer was defined as a lesion of the skin on the foot of a person who has diabetes [18] Impending ulcer was defined as callosities or nail changes in spots equal to the anatomical placement of ulcers associated with deformities.

Patients were examined after one week by an orthopedic surgeon and a podiatrist. Patients with diabetic foot ulcers were followed regularly until healing of the ulcers. The ulcer was defined as healed when it was covered with intact epithelium [20]. Patients with healed ulcers and patients with impending ulcers returned to normal outpatient clinical visit schedule, with close follow-up until optimal offloading of the feet. When optimal footwear and insoles were achieved, patients

#### Table 1

Baseline characteristics.

|   | Total               | Patients with ulcers | Patients without ulcers | P-Value |
|---|---------------------|----------------------|-------------------------|---------|
| Ν   | 81                  | 28                   | 53                      |         |
| Men   | 55 (68%)            | 24 (86%)             | 31 (58%)                | 0.01    |
| Age (years)   | $65.4 \pm 16$       | $62.8 \pm 9$         | $66.9 \pm 12$           | 0.04    |
| Diabetes duration (years)                                     | $26.4 \pm 16$       | $24 \pm 15.2$        | $27.7 \pm 16.4$         | 0.35    |
| Type 1 DM   | 27 (33%)            | 10 (36%)             | 17 (32%)                | 0.8     |
| Smoker  | 11 (14%)            | 3 (11%)              | 8 (15%)                 | 0.7     |
| Alcohol-abuse   | 10 (12%)            | 3 (11%)              | 7 (13%)                 | 1.0     |
| BMI (kg/m <sup>2</sup> )                                      | $30.5 \pm 5.4$      | $32.3 \pm 6.3$       | $29.6 \pm 4.6$          | 0.08    |
| Systolic BP (mmHg)  | $133 \pm 19$        | $135 \pm 21$         | $132 \pm 17$            | 0.6     |
| Diastolic BP (mmHg)   | 74 ± 9              | $73 \pm 10$          | 74 ± 9                  | 0.92    |
| HbA <sub>1c</sub> * (%, mmol/mol)                             | 7.9 ± 3.4 (63 ± 14) | 8.1 ± 3.3 (65 ± 13)  | 7.7 ± 3.5 (61 ± 15)     | 0.11    |
| eGFR $(ml/min/1,73 m^2)$                                      | $69.8 \pm 21.2$     | $68.8 \pm 20.6$      | $70.3 \pm 21.7$         | 0.6     |
| p-LDL (mmol/l) (median (Q1-3))                                | 1.9 (1.4–2.2)       | 1.9 (1.4–2.5)        | 1.9 (1.4–2.2)           | 0.8     |
| p-Triglycerides (mmol/l) (median (Q1-3))                      | 1.6 (1.0-2.4)       | 1.8 (1.2–2.6)        | 1.6 (0.9–2.4)           | 0.22    |
| Urine-albumin-creatinine ratio, median (mg/g) (median (Q1-3)) | 21 (7–91)           | 39 (10–314)          | 18 (5-65)               | 0.05    |
| Vibration threshold $> 25 V$                                  | 75 (93%)            | 28 (100%)            | 47 (89%)                | 0.9     |
| Vibration threshold $> 50 V$                                  | 57 (70%)            | 25 (89%)             | 32 (60%)                | 0.01    |
| Absent monofilament sensation on either foot                  | 60 (74%)            | 24 (86%)             | 36 (68%)                | 0.11    |
| Charcot foot  | 13 (16%)            | 5 (18%)              | 8 (15%)                 | 0.75    |
| No palpable pulse in either foot                              | 16 (20%)            | 6 (21%)              | 10 (19%)                | 0.77    |
| Follow-up (weeks)   | 97 ± 46.1           | $104.9 \pm 44.8$     | 92.9 ± 46.5             | 0.39    |
| Mors during follow up   | 8 (10%)             | 3 (11%)              | 5 (9%)                  | 1.0     |

Total and divided into patients with ulcers and patients without ulcers (Categorical data is given as number of patients with % in parenthesis. Continuous data is reported as mean with standard deviation if nothing else is noted).

Estimated glomerular filtration rate (e-GFR) is calculated from the chronic kidney disease epidemiology collaboration equation. p-LDL = plasma low density lipoproteins.

-LDL – plasma low density inpoproteins.

\* HbA1C is reported in NGSP (%) followed by IFCC (mmol/mol).

were seen at least once yearly for screening and follow up of foot complications in accordance with IWGDF guidelines [21,22].

The following data were extracted from the electronic patient records as the results closest to the date before the procedure: laboratory results, weight, height and BMI.

## Results

## Population

In total 81 patients were included with an average follow up of 97 weeks ( $\pm$  46.1). Three patients were excluded – one was lost to follow up (patient did not visit the clinic after procedure) and two were excluded due to the tenotomy procedure being converted to scalpel. The 81 included (68% male) had an average age of 65.4 years ( $\pm$  16), 33% had type 1 diabetes and 67% had type 2 diabetes. The average diabetes duration was 26.4 years ( $\pm$  16), HbA1c was 7.9% ( $\pm$  3.4) (63 mmol/mol ( $\pm$  14)), 70% had a vibration threshold > 50 V, 74% were not able to feel the monofilament, 20% had no palpable foot pulse in either foot and 16% had a prior diagnosis of Charcot's disease (Table 1). A total of 106 procedures were performed on the 81 identified patients. Procedures were defined as tenotomy of one to 10 toes performed at the same visit, tenotomies performed at later visits were counted as a new procedure.

Of the 106 procedures, 70 (66%) were performed due to only impending ulcer(s), and 36 procedures (34%) where performed due to an ulcer. Of the 36 procedures performed due to an ulcer, 14 had procedures performed for both active and impending ulcers on different toes, taking the total number of procedures performed due to impending ulcers to 84.

Patients had all toes on one or both feet operated during one procedure in 16 cases, while less than all toes on one or both feet were operated in the remaining 90 procedures.

## Procedure results

All 106 incisions healed without serious complications, i.e. dehiscence, infection or bleeding.

The treated ulcers had mean duration before procedure of 4.5

(2–8.5) weeks. A total of 34 (94%) of the preexisting ulcers healed, in an average of 28 days ( $\pm$  35.2), five of the patients with healed ulcers (15%) had recurrences of ulcers in the observation period.

Of the 84 procedures performed as preventive treatment of impending ulcer, six (7%) progressed to an active ulcer associated with hammer, mallet and claw toes. Of the six procedures a total of 7 out of 30 toes were affected (one patient had two toes affected). Four of the seven toes affected was the first toe, in the remaining three cases the second toe was affected. Five of the six patients affected reported, that they had not used the prescribed offloading footwear in the period leading up to ulceration. In the last case, the cause of ulcer was not discovered. All ulcers healed within the follow up period. There were no additional surgical procedures performed to offload the affected toes, but in all cases, patients were instructed to use offloading footwear at all times, and footwear was in all cases optimized for optimal offloading.

There were no serious complications related to the procedures defined as amputations, infections or bleeding. However, in the observation period, three (3%) of the operated patients incurred minor amputations and one (1%) incurred a major amputation not related to the procedure. Four (4%) procedures had to be performed again (re-tenotomy) due to insufficient primary procedure, 25 (24%) patients had transfer lesions, with seven (7%) patients incurring ulcers, and 18 (17%) had impending ulcers associated with hammer, mallet and claw toes. Four (4%) patients needed extensor tenotomy in addition to flexor tenotomy to correct deformity of the toe. A total of 14 (13%) patients reported transient plantar pain which subsided within 7–14 days (for an overview of results and results divided in patients with and without ulcers see Table 2.)

# Discussion

Our study is the first to describe flexor tenotomies done by needle and is the largest study to assess outcomes after tenotomies. The study is lacking a control group for comparison, however when data from the current study is compared to data from a previous study on tenotomies done by scalpel published from our institute [10], the background data is comparable and the results are comparable to the studies on tenotomies performed by scalpel published at our and other institutions,

## Table 2

Tenotomy characteristics.

|  | Total         | Patients with ulcers | Patients without ulcers | P-Value* |
|--|---------------|----------------------|-------------------------|----------|
| Ν  | 106           | 36                   | 70                      |          |
| Number of toes operated  | 293           | 62                   | 231                     |          |
| Offloading procedure of at least one toe   | 84            | 14                   | 70                      |          |
| Progression to active ulcer after preventive procedure of at least one toe per procedure | 6 (7%)        | 1 (7%)               | 5(7%)                   | 1.0      |
| Time of ulcer before tenotomy (weeks) (median(Q1-3))                                     | N/A           | 4.5 (2.0-8.5)        | N/A                     | N/A      |
| Ulcer healed   | N/A           | 34 (94%)             | N/A                     | N/A      |
| Mean time to ulcer healing (days)  | N/A           | $28 \pm 35.2$        | N/A                     | N/A      |
| Healing of incision  | 106 (100%)    | 36 (100%)            | 70 (100%)               | 1.0      |
| Mean time to Incision healing (days)   | $4.4 \pm 2.5$ | $4.3 \pm 2.5$        | $4.5 \pm 2.6$           | 0.36     |
| Ulcer diagnosis  | N/A           |                      | N/A                     | N/A      |
| Ischemic   |               | 3 (8%)               |                         |          |
| Neuropathic  |               | 28 (78%)             |                         |          |
| Neuro-ischemic   |               | 5 (14%)              |                         |          |
| Ulcer recurrence   | N/A           | 5*** (15%)           | N/A                     | N/A      |
| Transfer lesions   |               |                      |                         |          |
| Total  | 25 (24%)      | 12 (33%)             | 13 (19%)                | 0.43     |
| Ulcer  | 7 (7%)        | 5 (14%)              | 2 (3%)                  | 0.17     |
| Impending ulcer  | 18 (17%)      | 7 (19%)              | 11 (16%)                | 0.79     |
| Minor amputations  | 3 (3%)        | 1 (3%)               | 2 (3%)                  | 1.0      |
| Major amputation   | 1 (1%)        | 1 (3%)               | 0                       | 0.35     |
| Infections   | 0             | 0                    | 0                       | 1.0      |
| Re-tenotomi  | 4 (4%)        | 1 (3%)               | 3 (4%)                  | 1.0      |
| Extensor tenotomi  | 4 (4%)        | 0                    | 4 (6%)                  | 0.3      |
| Pain   | 14 (13%)      | 0                    | 14 (20%)                | 0.02     |

Total and divided into procedures on patients with ulcers and procedures on patients without ulcers.

\* P-value refers to patient with ulcers compared with patients without ulcers.

\*\* % of 84 offloading procedures.

\*\*\* Recurrence was calculated as 5/34, where the 34 is the 34 patients who achieved ulcer healing.

regarding percentages of ulcers healed, recurrence of ulcers and transfer lesions [10,17,23,25,26] (see Fig. 1).

It is important to note that 94% of treated ulcers healed in an average time of 28 days, that only 7% of the preventive procedures led to an active ulcer all of which healed in the follow up period, and that none of the 106 procedures led to serious complications associated to tenotomies i.e. amputations and infections.

Flexor tenotomy, whether performed by scalpel or needle, has been widely used in the management of diabetic foot deformities in many countries, and since the beginning of this millennium at our institute.

All previous studies on flexor tenotomies done by scalpel have

shown promising results but failed to reach an acceptable level of evidence to conclude, that tenotomies are a safe and effective treatment for hammer, mallet and claw toe deformities in patients with diabetes [11,12]. However, the procedure has been recommended under specific indications in international guidelines [21].

Of the 36 treated ulcers, 34 healed (94%). The two ulcers that did not heal were one salvage procedures, where proximal interphalangeal joint was already exposed at the time of procedure and lead to a toe amputation. The other non-healed ulcer was due to patient being lost to follow up, patient was admitted to hospital for medical treatment not related to the ulcer, and unfortunately died during the stay without the



Fig. 1. Comparison of outcomes. Comparison of outcomes between our study and five studies of tenotomies performed with scalpel [10,14,21-23].

ulcer being described during the period of admission. These results are comparable to the results from earlier studies done on tenotomies by scalpel (see Fig. 1)

Of the preventive procedures, six (7%) incurred an active ulcer, all of which healed in the follow up period. Earlier studies of tenotomies done by scalpel did not find any progression to active ulcers [23]. This could be explained by our larger population and long follow up. Furthermore, the prior articles on tenotomies done by scalpel have reported on single toes as a procedure, while we looked at one to 10 toes per procedure. If calculated per toe the percentage of toes that progressed to active ulcer from impending ulcer, dropped from 7% to 3%. Most importantly, we still have not seen a randomized comparative study on preventive tenotomies and offloading therapy compared to offloading therapy alone and therefore, do not know how many of the patients with impending ulcers would progress to active ulcers, over time, without tenotomies.

The incidence of complications was generally low, and a short learning curve was observed. The four re-tenotomies and the two procedures excluded due to conversion to scalpel, were all performed within the first three months after the procedure was undertaken at our institute. This indicates the presence of a learning curve for the surgeons, even though it was short. The main complications were transfer lesions, pain and recurrence of ulcers.

It should be noted that 4% of the patients had deformities that were evaluated by the treating surgeon as needing extensor tenotomy in addition to flexor tenotomy. Three of the four extensor tenotomies were performed at the same visit as the planned flexor tenotomies, and one was performed at the seven-day follow-up visit. The indication for extensor tenotomy included lateral deviation and/or hyperextension of the treated toe as evaluated by the treating surgeon. A recently published article advocated that extensor substitution, as defined by the McGlamry classification, could lead to insufficient results of a flexor tenotomy in up to 23% of the treated patients [24]. We did not classify according to McGlamry, as our hypothesis on the etiology of hammer, mallet and claw toe deformities of patients with diabetes is based on the neuropathy driven atrophy of intrinsic musculature, which does not correlate with McGlamry. However only 4% of the treated patients were deemed to have deformities requiring extensor tenotomies, and in none of the four patients with recurrence of ulcers were extensor tenotomies deemed necessary.

Transfer lesions were the most prevalent complications in this study and are known complications to tenotomy [11,12]. In our study 24% incurred transfer lesions. Transfer lesions were defined as ulcers or impending ulcers at predilections sites for ulcers associated with hammer,

# Table 3

Transfer lesions.

|                                    | Total        | Procedures on all toes | Procedures on some toes | P-Value* |
|------------------------------------|--------------|------------------------|-------------------------|----------|
| Ν                                  | 106          | 16                     | 90                      |          |
| Number of toes<br>operated         | 293          | 96                     | 197                     |          |
| Follow-up (weeks)                  | 97 (±46.1)   | 94.5 ( ± 39.3)         | 97.4 (±47.4)            | 0.92     |
| Healing of incision                | 106 (100%)   | 16 (100%)              | 90 (100%)               | 1.0      |
| Incision time to<br>healing (days) | 4.4 ( ± 2.5) | 5.1 ( ± 2.5)           | 4.3 ( ± 2.5)            | 0.26     |
| Transfer lesions                   |              |                        |                         |          |
| Total                              | 25 (24%)     | 0 (0%)                 | 25 (28%)                | 0.01     |
| Ulcer                              | 7 (7%)       | 0 (0%)                 | 7 (8%)                  | 0.59     |
| Impending Ulcer                    | 18 (17%)     | 0 (0%)                 | 18 (20%)                | 0.07     |
| Minor Amputations                  | 3 (3%)       | 1 (6%)                 | 2 (2%)                  | 0.39     |
| Major Amputation                   | 1 (1%)       | 0 (0%)                 | 1 (1%)                  | 1.0      |
| Infections                         | 0            | 0                      | 0                       | 1.0      |
| Re-tenotomi                        | 4 (4%)       | 0                      | 4 (4%)                  | 1.0      |
| Extensor Tenotomi                  | 4 (4%)       | 1 (6%)                 | 3 (3%)                  | 0.49     |
| Pain                               | 14 (13%)     | 4 (25%)                | 10 (11%)                | 0.22     |

Total and divided into procedures on patients who received tenotomy off all toes and less than all toes.

mallet and claw toes, occurring after tenotomy of other toes than the ones affected by transfer lesions, on the same foot. The transfer lesions were distributed in transfer ulcers (7%) or impending ulcers (17%) associated with hammer, mallet or claw toe deformities. Only three of the prior studies on tenotomies, done by scalpel, have reported incidences of transfer ulcers with similar results [10,17,23,25,26] (see Fig. 1). An interesting observation is that patients, who had tenotomies performed on all toes on a single or both feet, effectively eliminating risk of transfer lesions, did not have higher risk of complications when compared to patients receiving tenotomy of less than all toes on one of or both feet (see Table 3). When comparing transfer lesions between the patients receiving tenotomies of all toes with the group receiving tenotomies of less than all toes, there was no significant difference when transfer lesions were divided in transfer ulcers and impending ulcers (see Table 3). If transfer lesions were pooled together, there were significantly less transfer lesions in the 'all toes group' as compared to the 'less than all toes group' (p < 0.05). This indicates, that tenotomies of all toes on one or both feet can eliminate the risk of transfer lesions, thereby reducing the risk of new ulcers and the inherent risk of infections and amputations.

The reason for pain associated with tenotomies is not clear from this study. It might be due to the mechanical trauma of the needle in the soft tissue or associated with the retraction and bulking of the severed tendon at the metatarsal heads. In this study, 13% experienced pain, defined as patient reported pain associated with the procedure. It is worth noting that pain was only present in patients without ulcers, which could be explained by a higher number of patients with neuropathy and loss of sensibility in the group of patients with compared with the group without ulcers (vibration threshold > 50 V: 89% vs. 60% (p < 0.05)).

All recurrent ulcers (15%) healed in the follow-up period but needed additional offloading. The recurrence rate can be partially explained by lack of patient adherence to offloading regimes, which is a known challenge in the treatment of patients with diabetes, worsening outcomes for wound healing and recurrence [27,28]. At the same time tenotomies should be regarded as a tool to help offload patients with diabetes and hammer, mallet and claw toes, but some patients' ulcers or impending ulcers can have a multifactorial etiology and require additional surgical or conservative treatment.

No serious complications were associated to the tenotomy procedure, however three patients incurred minor and one patient major amputation not related to the procedure. One of the minor amputations were performed on the toe that was tenotomized, however as mentioned above, the proximal interphalangeal joint was already partially exposed at the time of the tenotomy and the procedure was performed as a salvage procedure to save the toe. The remaining amputations were performed due to other ulcers than the ulcers treated by tenotomies.

Table 4

Comparison between current and prior study baseline characteristics.

|   | Current<br>study | Rasmussen et al. 2013 [10] | Ratio |
|---|------------------|----------------------------|-------|
| Ν   | 81               | 38                         |       |
| Men   | 55 (68%)         | 30 (79%)                   | 0.9   |
| Age (years)                                     | 65.4             | 62.8                       | 1.0   |
| Diabetes duration (years)                       | 26.4             | 23.5                       | 1.1   |
| Type 1 DM                                       | 27 (33%)         | 14 (37%)                   | 0.9   |
| Smoker  | 11 (14%)         | 7 (18%)                    | 0.8   |
| Alcohol-abuse                                   | 10 (12%)         | 3 (11%)                    | 1.1   |
| BMI (kg/m <sup>2</sup> )                        | 30.5             | 32.2                       | 0.9   |
| HbA <sub>1c</sub> * (%, mmol/mol)               | 7.9 (63)         | 8.2 (66)                   | 1     |
| Vibration threshold $> 25 V$                    | 75 (93%)         | 34 (90%)                   | 1     |
| Vibration threshold > 50 V                      | 57 (70%)         | 31 (82%)                   | 0.9   |
| Absent monofilament sensation on<br>either foot | 60 (74%)         | 32 (84%)                   | 0.9   |
| Charcot foot                                    | 13 (16%)         | 3 (8%)                     | 2     |
| No palpable pulse in either foot                | 16 (20%)         | 7 (18%)                    | 1     |
| Follow-up (months)                              | 22               | 31                         | 0.7   |

When data from the current study is compared to data from a previous study on tenotomies done by scalpel published from our institute [10], the background data is comparable and the results are comparable to the studies on tenotomies performed by scalpel published at our and other institutes [10,17,23,25,26] (see Table 4 and Fig. 1).

Healing rates for ulcers associated with hammer, mallet and claw toe deformities were found to be high with a low incidence of progression from impending to active ulcer when tenotomy was performed prophylactically and with a low incidence of complication. The strength of the study is the large cohort, the close follow up, and all procedures being performed at the same institute. However, there are the inherent limitations of the case studies, with lack of control groups, missing randomization, and high risk of bias. Randomized clinical trials comparing tenotomies and offloading with offloading alone are still needed and under way at our institute.

# Contributors

All authors contributed in one or more of the following ways; Conception and design of study, acquisition, analysis and/or interpretation of data, drafting the article, or revising it critically for important intellectual content. Finally, all authors read and approved the final version of the article.

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# **Declaration of Competing Interest**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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