Biomechanical and musculoskeletal changes after flexor tenotomy to reduce the risk of diabetic neuropathic toe ulcer recurrence

Marieke A. Mens1 | Jaap J. van Netten2 | Tessa E. Busch-Westbroek2 | Sicco A. Bus2 | Geert J. Streekstra3 | Ruud H. H. Wellenberg1 | Mario Maas1 | Max Nieuwdorp4 | Sjoerd A. S. Stufkens5

Abstract
Objective: To assess the effect of flexor tenotomy in patients with diabetes on barefoot plantar pressure, toe joint angles and ulcer recurrence during patient follow-up.

Methods: Patients with a history of ulceration on the toe apex were included. They underwent minimally invasive needle flexor tenotomy by an experienced musculoskeletal surgeon. Dynamic barefoot plantar pressure measurements and static weight-bearing radiographs were taken before and 2–4 weeks after the procedure.

Results: A total of 14 patients underwent flexor tenotomy on 50 toes in 19 feet. There was a mean follow-up time of 11.4 months. No ulcer recurrence occurred during follow-up. Mean barefoot plantar pressure was assessed on 34 toes and decreased significantly after the procedure by a mean 279 kPa (95% CI: 204–353; \( p < 0.001 \)). Metatarsophalangeal, proximal interphalangeal and distal interphalangeal joint angles were assessed on nine toes and all decreased significantly (by 7° [95% CI: 4–9; \( p < 0.001 \)], 19° [95% CI: 11–26; \( p < 0.001 \)] and 28° [95% CI: 13–44; \( p = 0.003 \)], respectively).

Conclusion: These observations show a beneficial effect of flexor tenotomy on biomechanical and musculoskeletal outcomes in the toes, without ulcer recurrence.

KEYWORDS
diabetes complications, diabetic foot, diabetic neuropathies, hammer toe syndrome, tenotomy
1 | INTRODUCTION

Toe ulcers frequently develop in people with diabetes-related peripheral neuropathy, especially in the case of toe deformity.\textsuperscript{1,2} These ulcers negatively impact quality of life and can lead to amputations, which may be prevented with proper preventive measures.\textsuperscript{3–6} Common deformities concern a hyperextension of the metatarsal phalangeal joint (MTPJ) and a hyperflexion of the proximal and distal interphalangeal joints (PIPJ and DIPJ).\textsuperscript{7} These deformities often result in increased mechanical pressure underneath the apex of the toes, increasing the likelihood of ulceration.\textsuperscript{8} To prevent ulcer recurrence, international guidelines recommend to consider a digital flexor tenotomy.\textsuperscript{1,9,10} However, this recommendation is based on low quality of evidence.\textsuperscript{9} The only evidence available has been obtained from selected participants in seven retrospective cohort studies, showing 0%–20% ulcer recurrence in a total 231 participants during a mean follow-up period of 11–31 months.\textsuperscript{10} Despite the limited evidence, the rationale for surgical eligibility lies in the presumed biomechanical effect, and the limited likelihood for harms associated with this minimally invasive procedure. It is suggested to establish a lasting off-loading effect of the toes, with people not requiring medical devices such as toe orthoses for off-loading. Further, it can be performed in the out-patient clinic, with no need for generalised anaesthesia or subsequent immobilisation and a low risk of complications.\textsuperscript{11} However, biomechanical and musculoskeletal changes following tenotomy, suggested as causative mechanisms for the clinical outcomes, have never been investigated.

In our clinic, we obtained biomechanical and musculoskeletal outcomes before and after this procedure as part of regular clinical care. This provided the unique opportunity to quantify changes in outcomes in a controlled pre–post study design. As such, we aimed to investigate the effect of flexor tenotomy in participants with diabetes on barefoot plantar pressures, toe joint angles and ulcer recurrence during follow-up.

2 | METHODS

We consecutively included all participants who were eligible and thus underwent flexor tendon tenotomy to help prevent recurrent ulceration. Selection criteria concerned a confirmed diagnosis of diabetes mellitus and peripheral neuropathy, non-rigid toe deformity, a healed ulcer and abundant callus on one or more toe apices. All surgical procedures were performed by one orthopaedic surgeon specialised in the foot and ankle (SASS). Before and 2–4 weeks after the procedure, barefoot plantar pressure during walking was measured using a pressure-sensitive plate (EMED-X, Novel GmbH, Munich, Germany) and weight-bearing radiographs were acquired. For plantar pressure, a two-step protocol with four trials per foot was used, which provides reliable pressure data with the minimum amount of steps necessary.\textsuperscript{12} Walking speed was self-selected. Primary outcome was the difference in peak plantar pressure at the hallux, digitus 2 or digitus 3 pre- and post-surgery, using analysis-software provided by the manufacturer; the average of pressure over the four measurements across trials were used as outcome. Assessing barefoot plantar pressure in digitus 4 and 5 was not possible due to limitations of the analysis-software. A sub-analysis of barefoot plantar pressure of one toe per participant was conducted to limit bias in the conclusions drawn from using multiple toes and feet per participant.\textsuperscript{13} We selected the toe with the highest plantar pressure before the flexor tenotomy for this sub-analysis.

For radiographs, primary outcome was the difference in the angle of the MTPJ, PIPJ and DIPJ of digitus 2 pre- and post-surgery, as determined by drawing centre lines of the metatarsal and phalanges using IMPAX (Agfa IMPAX 6) by a researcher (MAM) and checked by an experienced musculoskeletal radiologist (MM). This method of measuring joint angles in the toes has proven reliable on MRI.\textsuperscript{14} Only digitus 2 was suitable for radiographic assessment, because overlap of the toes made measurements on the other toes inaccurate or sometimes impossible. As part of regular care, participants had frequent check-ups after the procedure to identify recurring ulcers and complications.

Ethical approval was waived in accordance with Dutch law by the medical ethical committee of our institute (W21_080#21.090) on the grounds that no changes were made to the normal procedure in the clinic. Oral informed consent was obtained from all participants for the procedure, data analysis and reporting.

What’s new?

Minimally invasive needle flexor tenotomy is a promising surgical technique for preventing diabetic ulcer recurrence at the apex of the toes in patients with toe deformity. This study investigated the biomechanical and musculoskeletal changes after this operation. Barefoot plantar pressure and toe joint angles both decrease significantly after the flexor tenotomy. Additionally, there were no recurring ulcers on the operated toes. Thus, this study provides additional substantiation of considering flexor tenotomy in this patient population.
3 | RESULTS

A total of 14 participants underwent flexor tenotomy on a total of 50 deformed toes in 19 feet, between November 2019 and December 2020 (Table 1). This included 16 digits 4 and 5, thus 34 toes were used for barefoot plantar pressure analysis. Barefoot plantar pressures decreased with a statistically significant 279 kPa (95% CI: 204–353 kPa, p < 0.001; Table 2; Figure 1), and the decrease was seen at all anatomical locations (Table 2). When analysing only one toe per participant, there was a statistically significant reduction in plantar pressure of 398 kPa (95% CI: 285–511 kPa, p < 0.001; Table 2). MTPJ, PIPJ and DIPJ angles decreased with a statistically significant 7° (95% CI: 2°–9°; p < 0.001), 19° (95% CI: 11°–26°; p < 0.001) and 28° (95% CI: 13°–44°; p = 0.003; Table 2; Figure 1), respectively. On average, participants’ most recent foot ulcer took 3 months to heal, and participants were ulcer-free for 3 months at the moment of surgery (Table 1). The most recent ulcer was not necessarily on one of the treated toes.

Before surgery, nine participants were wearing custom-made insoles worn in custom-made shoes, two participants wore custom-made insoles in pre-fabricated extra-depth shoes, three used inlays in pre-fabricated shoes. After 6 months of follow-up all participants wore custom-made insoles in either custom-made shoes or pre-fabricated extra-depth shoes. Concerning orthoses, seven wore orthoses before the surgery, they all stopped wearing them on the treated toe(s) after the procedure. During a mean follow-up period of 11.4 months (SD:4; range: 2–19), no ulcer recurrences were observed, one foot complication was found (persisting MTPJ hyperextension) and one patient died 2 months after the tenotomy, unrelated to the surgery.

4 | DISCUSSION

This study aimed to assess the effect of minimally invasive needle flexor tenotomy in participants with diabetes on barefoot plantar pressure, toe joint angles and ulcer recurrence during follow-up.

Our findings show a large off-loading effect, with >50% pressure reduction at the toe apex, in line with the hypothesised causative mechanism of this minimally invasive surgery in ulcer prevention. The radiological data demonstrate the musculoskeletal changes that show the mechanism behind the pressure reduction. There was no ulcer recurrence among the participants after almost a year, which is remarkable considering the high recurrence rates of ulcers in the first year after healing.1

Clinical outcomes are in line with current evidence on the benefit of this surgery for the prevention of ulcer recurrence.10 Five of the seven patients wearing orthoses on toes with deformity before the surgery stopped wearing them afterwards. This was to be expected, because the surgery is supposed to diminish the severity of the deformity. Patients not needing to wear their orthosis after surgery reflects this positive change in the toe.

In this study, the participants used specialised orthopaedic footwear for off-loading in addition to the surgical intervention and continued to wear this after

### Table 1 Demographics at baseline

| Demographics                           | N = 14 |
|----------------------------------------|--------|
| Participants                           | 10/4   |
| Sex (men/women)                        | 68 ± 10|
| Age (years)                            | Type 1: 14% (n = 3); Type 2: 86% (n = 11) |
| Diabetes duration (years)              | 13 ± 11|
| Peripheral artery disease              | 50% (n = 7) |
| Most recent foot ulcer                 | 21% (n = 3)/36% (n = 5)/29% (n = 4)/14% (n = 2) |
| Location: Hallux/dig 2/3/4             | 14 ± 16|
| Healing time (weeks)                   | 14 ± 28|
| Time between healing and surgery (weeks)| 14 ± 28|
| Treated feet                           | N = 19 |
| Left/right/both                        | 7% (n = 1); 57% (n = 8); 36% (n = 5) |
| Treated toes                           | N = 50 |
| Hallux/dig2/3/4/5                      | 4% (n = 2)/38% (n = 17)/30% (n = 15)/18% (n = 9)/14% (n = 7) |

Note: Data are mean ± SD, percentage (%) or n (number of participants or digits).

*Peripheral artery disease was never critically ischemic (i.e. toe pressure <30 mmHg or ankle-brachial index <0.5), since this is a contraindication for flexor tendon tenotomy.
the procedure. It is advised that patients keep using off-loading measures considering the available evidence about its benefits.\textsuperscript{15,16} However, there should be an assessment of footwear after this procedure has been performed because of the alterations in lesser toe barefoot pressure. Participants of our study had regular checks of the in-shoe pressure to monitor if changes in footwear were needed.

A strength of our study is the use of objective biomechanical and musculoskeletal tests to demonstrate the causative factors of off-loading with flexor tenotomy. A limitation was the overlap of toes on radiographs. As a result, we could only investigate musculoskeletal changes in digitus 2. This can be resolved by using three-dimensional imaging. Analysing barefoot pressure separately for digitus 4 and 5 was not possible. However, the visual rendition

\begin{table}
\centering
\caption{Biomechanical and musculoskeletal outcomes before and after flexor tenotomy}
\begin{tabular}{|l|cc|c|c|}
\hline
Outcomes & Pre-tenotomy & Post-tenotomy & Mean difference (95\% CI) & \textit{p}-value & Cohen’s \textit{d}  \\
\hline
Barefoot plantar pressure (kPa) & & & & & \\
All analysed toes (\(n = 34\)) & 432 ± 258 & 153 ± 100 & 279 (204; 353) & <0.001 & 1.3  \\
Hallux (\(n = 2\)) & 773 ± 228 & 354 ± 73 & 419 (NA) & NA & 1.4  \\
Digitus 2 (\(n = 17\)) & 515 ± 264 & 175 ± 101 & 340 (220; 459) & <0.001 & 1.5  \\
Digitus 3 (\(n = 15\)) & 292 ± 158 & 101 ± 45 & 191 (105; 276) & <0.001 & 1.2  \\
Digitus with highest pressure pre-tenotomy (\(n = 14\)) & 593 ± 222 & 195 ± 95 & 398 (285; 511) & <0.001 & 2.0  \\
\hline
Digitus 2 joint angle (°) & & & & & \\
MTPJ (\(n = 9\)) & 31 ± 9 & 24 ± 10 & 7 (4; 9) & <0.001 & 1.8  \\
PIPJ (\(n = 9\)) & 48 ± 23 & 29 ± 17 & 19 (11; 26) & <0.001 & 1.7  \\
DIPJ (\(n = 9\)) & 51 ± 8 & 22 ± 23 & 28 (13; 44) & 0.003 & 1.4  \\
\hline
\end{tabular}
\end{table}

Note: Data are mean ± SD or \(n\) (number of participants or digits); to test for significance (\textit{p}-value) a dependent samples \(t\)-test was used; to test for effect size within-subject Cohen’s \textit{d} was calculated (https://memory.psych.mun.ca/models/stats/effect_size.shtml).

Abbreviations: DIPJ, distal interphalangeal joint; MTPJ, metatarsal phalangeal joint; NA, not applicable, due to having only 2 operated hallucae; PIPJ, proximal interphalangeal joint.

\begin{figure}
\centering
\includegraphics[width=\textwidth]{image1.png}
\caption{Barefoot plantar pressure from one step and radiograph of the right foot of a participant before and after flexor tenotomy on digitus 2, 3, 4 and 5. Barefoot plantar pressure underneath the apex of digitus 2 was 565 kPa before flexor tenotomy and 146 kPa after flexor tenotomy. DIPJ angle of digitus 2 was 49.2° before flexor tenotomy and 30.8° after flexor tenotomy.}
\end{figure}
of the barefoot pressure showed similar effects of the surgery for these toes as for the hallux and digits 2 and 3. Improved software could solve the limitations on assessing barefoot pressure on digits 4 and 5. Another limitation was that radiographs both before and after the flexor tenotomy were available for nine of the 17 operated digits. This was mainly because radiographs were not always routinely performed in the clinic both before and after the procedure. In addition, some images were not suitable for the measurements, for example because the toes were not in the field-of-view or because the lateral view was not available. While including 14 participants could be seen as a limitation, these participants represent a total 34 analysed toes; more importantly the large, consistent and statistically significant differences found on the primary biomechanical and musculoskeletal outcomes indicate that including a larger group of participants would have resulted in similar findings.

In conclusion, these observations provide first-ever quantitative demonstrations of the effect of flexor tenotomy on plantar pressure reduction and joint angle decreases (i.e. improvement) in the toes of people with diabetes. Very low ulcer recurrence was found. Future randomised controlled trials are needed to confirm these outcomes.

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CONFLICT OF INTEREST
None to disclose.

ORCID
Marieke A. Mens https://orcid.org/0000-0002-6094-2417
Jaap J. van Netten https://orcid.org/0000-0002-6420-6046
Sicco A. Bus https://orcid.org/0000-0002-8357-9163

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