PEDORTHIC
ASSOCIATION OF CANADA

The Pedorthic Association of Canada (PAC)
Patient Outcome Measure Evaluation Strategy (POMES):
The Patients' Perspectives on the
Effectiveness of Custom Made Foot Orthotics

White Paper

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Introduction

This project was initiated by the Pedorthic Association of Canada (PAC). The need for the study arose out of the observation that there was very little objectively solicited patient feedback on the use of custom made foot orthotics (CMFOs) by Canadians. The information that the patients provided was very useful for those with foot pain or discomfort, PAC as well as its membership. The project was a multi-centered, internet-based short self-report survey of patients' perspectives pre- and post-use of (CMFOs). Patients were asked to complete a self-report survey on a tablet or personal computer after a CMFO assessment (pre-use survey) by a Canadian Certified Pedorthist (C. Ped (C)). Pedorthists, working out of 23 clinics in 4 provinces (Alberta, British Columbia, Ontario and Nova Scotia) recruited 217 CMFO patients over the course of 12 months. After six (6) weeks of CMFO use, patients were asked to complete a second survey (post-use survey). The results of the two surveys were compared to answer the objectives and purpose of the project.

Type of Project and Background of Project

This quality assurance/quality improvement project is designed to solicit objective feedback from patients who have received custom made foot orthotics (CMFOs) from a Canadian Certified Pedorthist (C. Ped (C)). The design of the project is a short survey administered pre-/post-use of CMFOs. The impetus of the project arose from the Pedorthic Association of Canada (PAC) memberships, who were searching for an objective way to solicit feedback from patients using CMFOs.

Relevance of the Project

The project is relevant to several stakeholders, including those impacted by foot and ankle pain or discomfort, PAC as well as its membership. The insurance industry and employee benefit plan administrators and sponsors may also see relevance in the outcome of the project.

Literature Review

Current best practice for several foot and ankle conditions is the prescription of custom made foot orthotics (CMFOs) for the relief of pain or discomfort, as well as to facilitate movement and activities of daily living or sporting activities (Hawke et al., 2008, Hume et al., 2008, Henessey et al., 2012, Burns et al., 2009, Drake et al., 2011). Unfortunately, as with many treatments, modalities and interventions available to practitioners, there may be limited information on functional, objective and empirical evidence to support their use in some cases. There is even more limited information from the patients' perspective, particularly as it applies to their thoughts and beliefs in relation to their response to care plans. If one combines the limited evidence in some cases, and the limited objectively solicited information from a patients' perspective, one arrives at a compelling project question from a community point of view.

This project was designed to solicit feedback, in an objective manner, using previously validated and efficacious tools, about the patients' perspective concerning the usefulness of CMFOs with regards to several key outcome measures, including pain or discomfort, and activity level pre- and post-use.

There are very few recent Canadian studies that have been published in the peer-reviewed literature on the issue, and some studies are limited to very specific conditions (Amell et al., 2000, Powell et al., 2005). There are some relevant results from recent work, however they involve custom made orthopaedic shoes rather than custom made foot orthotics (van Netten et al., 2009, 2010a, 2010b, 2010c and 2012).

Specific Study Questions and Objectives

The purpose of the project was to solicit feedback, in a structured, coordinated and objective manner, about the patients' perspectives on Custom Made Foot Orthotics (CMFOs) and how their usage impacts upon the daily lives of patients.

The objectives are twofold. We are seeking to answer the following questions from the patients' perspective. Does the use of CMFOs help to:

1. Reduce pain or discomfort in the foot and ankle with regular use; and
2. Allow users to increase their level of activity?

Project Methods

Design and Analysis

The project design was a multi-centered, internet-based short self-report survey of patients' perspectives pre- and post-use of custom made foot orthotics (CMFOs). Patients were asked to complete a self-report survey on a tablet or personal computer after a CMFO assessment (pre-use survey) by a Canadian Certified Pedorthist (C. Ped (C)). After six (6) weeks of CMFO use, patients were asked to complete a second survey (post-use survey). The results of the two surveys were compared to answer to the objectives and purpose of the project.

The short survey tool (see appendix) is a slightly modified version of an existing, validated tool (van Netten et al., 2009). The original version was administered to patients using custom made orthopaedic shoes, and slight modifications were required to allow the tool to be effectively administered to users of custom made foot orthotics. None of the modifications impacted the validity or reliability of the survey.

Key elements of the dataset were short survey responses that are either mutually exclusive or multiple response sets. Ten (10) point Likert scale responses were used throughout the survey for pain or discomfort questions, as well as other perception and activity questions. Some open-ended responses were also included, which were reviewed and reported on anecdotally.

In terms of how these data were analyzed, data were extracted from the custom-created database, scrubbed of any personal identifiers of the users (anonymization process) and analyzed using IBM SPSS version 21. Arithmetic means as well as paired sampled t-tests were used to determine the statistical significance of differences between the primary and secondary outcome measures in the pre- and post-use data. Outcome data were tested against the 0.05 α level of statistical significance.
This process enabled the research team and PAC advisory group to achieve the goals of the project and help better understand the patients' perspectives on CMFOs.

Inclusion Criteria

1. The project was limited to adults between the ages of 18 and 65 years at the time of the assessment;
2. All Custom Made Foot Orthotics (CMFOs) patients presenting with a musculoskeletal condition below the knee;
3. All patients provided informed consent to provide feedback to the project.

Exclusion Criteria

1. Inability to read and understand the English language;
2. Patients with diabetes with neuropathy, foot ulcers and similar conditions;
3. Patients with rheumatoid arthritis;
4. Patients with a muscle disease.

Data Collection

The pre- and post-use of CMFOs data were collected from project participants via an internet-based short survey. Demographic and orthotic specific data were collected from Canadian Certified Pedorthists using the same method.

The primary outcome variables were foot and ankle pain or discomfort pre- and post-use of Custom Made Foot Orthotics (CMFOs), measured via self-report on a 10-point Likert scale via an internet-based customized survey tool.

The secondary outcome variables were activity levels pre- and post-use of Custom Made Foot Orthotics (CMFOs), measured via self-report on a 10-point Likert scale via an internet-based customized survey tool.

CMFO Intervention

The intervention is the use of custom made foot orthotics (CMFOs) for the relief of pain or discomfort in the feet or ankles. To obtain CMFOs, a prescription is sometimes required from a referring physician, and the cost of the intervention may or may not be covered by public health insurance or employer sponsored group benefit insurance plans.

CMFOs are shoe inserts, constructed of a variety of different materials. They are constructed based upon the biomechanical principles of maintaining support for the arch of the foot, and an optimal foot position, comfort, among others. They are customized to the specific needs of the patient via a three-dimensional model (3D) of the foot in order to use the raw materials to craft a specific, unique orthotic for the individual that accommodates the unique needs of the patient. Custom made foot orthotics are contrasted with over the counter devices which are not patient-specific in nature.

Ethical Considerations

Since the project was carried out as an evaluation of current practices related to the use of CMFOs, and is philosophically a quality assurance/quality improvement project, there are very few ethical considerations beyond the protection of personal information and privacy in relation to survey responses. Strict measures were taken to ensure anonymity of participants, and their responses. All analysis took place on scrubbed data and was processed through a rigorous anonymization process.

Ethical clearance for this project as was obtained through the Health Research Ethics Board of Alberta (HREBA) - Community Health Committee.

Results

The Impact of CMFOs on Pain and Activity

The patient outcomes were divided into two groups, the self-report survey outcomes pre- and post-use of CMFOs. A third group of responders, Pedorthists, provided qualifying information on the type of CMFO as well as useful ancillary information. The response rate is provided in table 1. Table 2 lists the referral source for the CMFO and the primary reason for obtaining CMFO at this time.

Table 1. PAC-POMES Response Rate.

	Number of Responses	**Percentage**
Pre-CMFO use	130	60%
Post-CMFO use	68	31%
Pedorthist	217	100%

Table 2. Referral source for the CMFO and the primary reason for obtaining CMFOs at this time.

Referral Source for CMFO	**Percentage**
Family physician	72%
Rehabilitation or specialist physician (e.g. sports medicine physician, physiatrist, etc.)	15%
Other (Chiropractor, Kinesiologist, Nurse etc.)	9%
Orthopedic surgeon	3%
Rheumatologist	1%
Primary Reason for CMFO	
Pain or numbness in feet or ankles	64%
Replacing a worn out or lost pair of orthotics I had previously been using on a regular basis	21%
Other (Back pain, knee pain, calf pain etc.)	14%
Difference in leg length	2%

In those 21% of patients who were replacing CMFOs, their frequency of use was greater than 4 days per week in 100% of respondents and 92% indicated that their pain or discomfort was reduced when they were wearing CMFOs. Similarly, 73% of patients indicated that their pain or discomfort returned when they were not wearing CMFOs.

With regards to the primary purpose of the PAC-POMES initiative, which was to determine the patients' perspectives on the impact that CMFOs had on the r*eduction of pain or discomfort in the foot and ankle*

with regular use, the results are conclusive, as shown in table 3. These results are conclusive even when adjusted for patient response rate and only focusing upon those patients who completed both the pre- and post-CMFO surveys.

Similarly, 91% of patients reported a reduction in pain after wearing their CMFO's for six (6) weeks.

Table 3. Mean self-reported pain or discomfort value on a 10 point scale, where 1 was 'no pain or discomfort' and 10 was 'very much pain or discomfort.'

	Mean Self-Reported Pain or Discomfort (1-10 scale)	**Percentage Difference**
All Patient Data*		
Pre-CMFO use	5.22	36% Reduction in Pain or Discomfort
Post-CMFO use	3.36	
Difference	**1.86†**	
Complete Patient Data**		
Pre-CMFO use	4.99	33% Reduction in Pain or Discomfort
Post-CMFO use	3.36	
Difference	**1.63†**	

* All patient data refers to all respondents who completed either/or the pre- and post- surveys
** Complete patient data refers to only those completing the post-survey (who also completed the pre-survey)
† Indicates Statistical Significance at .05 a level in a paired samples t-test

While the arithmetic means are useful for determining percentage reduction in pain or discomfort, more advanced paired-samples t-tests were used to determine the statistical significance of any differences between the primary outcome measure in the pre- and post-use data. These results are statistically significant when tested against the 0.05 α level of significance, indicating a strong relationship between CMFO use and reduction in pain or discomfort. The same results were obtained with the data were stratified by pain in relation to activities such as work and sport. The results are listed in table 4.

Table 4. Results of the paired sampled t-test conducted upon all pre-post CMFO patients in relation to pain reduction.

Paired Differences							
			95% Confidence Interval of the Difference				
Mean	**Std. Deviation**	**Std. Error Mean**	**Lower**	**Upper**	**t**	**df**	**Sig. (2-tailed)**
-1.618	2.71	0.329	-2.274	-0.962	-4.922	67	0.000

With regards to CMFO usage in comparison to various activities, the majority of patients reported lower pain levels following six (6) weeks of usage. Table 5 summarizes the results.

Table 5. Comparison of pain level by type of activity.

	During work duties	**During hobbies**	**During standing and walking**	**During sport**	**During a walk**
lower pain level	60%	59%	68%	68%	59%
no change in pain level	21%	24%	15%	13%	19%
higher pain level	19%	18%	18%	19%	22%

With regards to the secondary purpose of the PAC-POMES initiative, which was to determine the patients' perspectives on the impact that CMFOs had on their ability to *increase their level of activity with regular use,* the results are conclusive, as shown in table 6. As with the primary purpose, these results are conclusive even when adjusted for patient response rate and only focusing upon those patients who completed both the pre- and post-CMFO surveys.

Table 6. Responses to the post-CMFO survey question "Compared with the period before you received your Custom Made Foot Orthotics, your maximum walking capacity..."

Response…	**Percentage**
…is improved, because of the Custom Made Foot Orthotics	64%
…has not changed	28%
…is improved, but not because of the Custom Made Foot Orthotics	4%
…has deteriorated, but not because of the Custom Made Foot Orthotics	3%
…has deteriorated, because of the Custom Made Foot Orthotics	1%

Due to the observation period being six (6) weeks between pre- and post- surveys, one can surmise that a longer observation period would have resulted in even more improvement.

Sixty-two respondents answered 7 or higher on a 10 point likert scale when asked about their ability to walk post CMFO usage. This equates to 90% of patients reporting that they are able to walk very well while wearing their CMFOs. Related to the issue of the ability to increase their level of activity is the perception of comfort. Seventy-seven (77%) of patients reported that their CMFOs were very comfortable, measured by a score of 7 or higher on a 10 point likert scale.

Similarly, another related issue to activity and comfort is the notion of frequency of wearing CMFOs. Eighty-three percent (83%) of patients were very satisfied with how often they were wearing their CMFOs.

Patient Expectations and Goals

The patients were asked several questions in relation to the expectations and goals of their CMFOs and their experience. During the pre-CMFO survey, 91% of patients expected a reduction in the level of pain and discomfort they experience, as defined by a value of < 5 on the 10 point scale. This value is quite similar to the achieved results. Similarly, patients were more active than expected after six (6) weeks of CMFO usage (Table 7).

Ninety-eight percent (98%) of patients indicated that their Pedorthist listened to their needs, and after their assessment, 90% of patients expected more from the CMFOs. In addition, 81% of patients indicated that their goals were met after six (6) weeks of using CMFOs.

Although patients recognized that there were some disadvantages to requiring CMFOs, six (6) weeks after wearing CMFO's 93% of patients felt that the advantages of CMFO's certainly outweighed the disadvantages.

Table 7. Responses to the post-CMFO survey question "While wearing your Custom Made Foot Orthotics, do you perform the following activities less or more than you expected?"

Activity Type	More Activity than Expected	No Change in Activity over Expected	Less Activity than Expected
Going for a walk:	51%	41%	7%
Participating in sport:	44%	51%	4%
Going shopping in town:	37%	59%	4%
Shopping for groceries:	32%	65%	3%
Performing work duties:	32%	65%	3%
Walking around the garden:	21%	78%	1%
Housekeeping jobs:	21%	78%	1%
Participating in hobbies:	26%	72%	1%
Walking inside the house:	18%	81%	1%

Patient Recommendations and Perceptions on Insurance Coverage

Patient recommendations were sought in the post-CMFO survey, and 87% responded with a 7 or higher on a 10 point scale (from very unlikely to very likely) that they would recommend CMFOs to family, friends or colleagues. The proportion of patients indicating that their CMFOS were covered by insurance, either in whole or in part was 85%, with only 10% of patients indicating an out of pocket expense without any coverage (Table 9).

Table 9. Responses to the post-CMFO survey question inquiring about the nature of insurance coverage for CMFOs.

The Cost of my CMFOs was…	Percentage
Paid by me or another family member and my costs will be / have been **FULLY** reimbursed by my insurer (covered by extended health benefit, paramedical health benefit coverage etc.).	19%
Paid by me or another family member and my costs will be / have been **PARTIALLY** reimbursed by my insurer (covered by extended health benefit, paramedical health benefit coverage etc.).	59%
Paid by me or another family member and my costs **WILL NOT BE / WERE NOT** reimbursed by my insurer (not covered by extended health benefits, paramedical health benefits etc.).	3%
Paid directly by my insurance coverage (direct billing).	7%
Paid directly by me or another family member.	10%
Paid directly through government assistance/social services.	0%
Other (Complimentary)	1%

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Appendices

Appendix A – Patient Surveys

Pre-Custom Made Foot Orthotic Use Survey
Administered at Assessment

Background Information

1. Which **healthcare professional** prescribed your **Custom Made Foot Orthotics**?
   - Rehabilitation or specialist physician (e.g. sports medicine physician, physiatrist etc.)
   - Family physician
   - Orthopaedic surgeon
   - Rheumatologist
   - Other, please specify: ……

2. What is the **most important** reason for you receiving **Custom Made Foot Orthotics**? Choose the most appropriate answer.
   - Pain or numbness in feet or ankles
   - Difference in leg length
   - Replacing a worn out or lost pair of orthotics I had previously been using on a regular basis
   - Other, please specify: ……

Current Situation

If participant is replacing a worn out our or lost pair, the following 4 questions apply. Yes (if yes, I am replacing an existing pair which has worn out, and please proceed to the following question) or No (if no, this is my first pair of custom made foot orthotics or I have not used them in a long time, and please proceed to question 7).

3. How often do you wear your **Custom Made Foot Orthotics**?
   - 6 – 7 days per week
   - 4 – 5 days per week
   - 2 – 3 days per week
   - 1 day per week

4. If you wear your **Custom Made Foot Orthotics**, how many hours a day do you wear them?
   - more than 12 hours
   - 8 – 12 hours
   - 4 – 8 hours
   - 1 – 4 hours

5. Is your pain or discomfort reduced when you are wearing your **Custom Made Foot Orthotics**?
   - Yes
   - No

6. Does your pain or discomfort return when you are not wearing your **Custom Made Foot Orthotics**?
   - Yes
   - No

7. What is your current **maximum walking capacity**? Choose the most appropriate answer.
   - I can walk inside my house (0 – 10 meters)
   - I can walk to the neighbour's house (10 – 50 meters)
   - I can walk to the corner of the street (50 – 200 meters)
   - I can walk to shops etc. in the neighbourhood (200 meters – 1 kilometre)
   - I can walk a fair distance without rest (more than 1 kilometre)

8. Which of the following symptoms do you believe your **Custom Made Foot Orthotics** will help alleviate? (Please select all that apply)
   - Heel pain
   - Forefoot pain (ball of the foot)
   - Arch pain
   - Toe pain (which toe)
   - Numbness/tingling
   - General foot pain
   - Ankle pain

9. Indicate the amount of **pain or discomfort** you feel in your feet and / or ankles during activities like standing and / or walking.

None Very much

10. Please indicate the amount of pain or discomfort **you currently feel** during the following activities.

- walking inside the house:	**10cm sliding scale from used in question 9 from pre survey.**
- walking around the garden:	**10cm sliding scale from used in question 9 from pre survey.**
- housekeeping jobs:	**10cm sliding scale from used in question 9 from pre survey.**
- shopping for groceries:	**10cm sliding scale from used in question 9 from pre survey.**
- performing work duties:	**10cm sliding scale from used in question 9 from pre survey.**
- participating in hobbies:	**10cm sliding scale from used in question 9 from pre survey.**
- going shopping in town:	**10cm sliding scale from used in question 9 from pre survey.**
- going for a walk:	**10cm sliding scale from used in question 9 from pre survey.**
- participating in sport:	**10cm sliding scale from used in question 9 from pre survey.**

11. Please indicate the location of your **pain** or **discomfort** with a cross**.**
I have no pain radio button.

Image of foot and pain location.

Expectations of your Custom Made Foot Orthotics

12. When wearing your **Custom Made Foot Orthotics**, do you expect to have **less or more pain or discomfort** in your feet and / or ankles, during activities like standing and / or walking? Indicate the amount of change in pain or discomfort you expect.

much less ⊢——————————————⊣ much more

Discussion of your expectations with the Pedorthist

13. Indicate how well the **Pedorthist** listened to you.

very poorly ⊢——————————————⊣ very well

14. Did the **Pedorthist** discuss what you can and cannot expect from your **Custom Made Foot Orthotics**?
    - yes (if yes, continue with question 15)
    - no (if no, continue with question 16)
    - I cannot remember (if you cannot remember, continue with question 16)

15. Did you adjust your expectations following discussions with **the Pedorthist**?
    - yes, I now expect more of my **Custom Made Foot Orthotics**
    - yes, I now expect less from my **Custom Made Foot Orthotics**
    - no, I still expect the same
    - I did not have any expectations

Use of your Custom Made Foot Orthotics

16. Indicate how comfortable you **expect** that your **Custom Made Foot Orthotics** will **feel.**

very uncomfortable ⊢——————————————⊣ very comfortable

17. **How much** do you **expect** to be able to **walk (at a maximum)** while wearing your **Custom Made Foot Orthotics**? (Choose the most appropriate answer)

I expect that I will be able to…
- ... walk inside my house (0 – 10 meters)
- ... walk to the neighbour's house (10 – 50 meters)
- ... walk to the corner of the street (50 – 200 meters)
- ... walk to shops etc. in the neighbourhood (200 meters – 1 kilometre)

- ... walk a fair distance without rest (more than 1 kilometre)

18. Is that less or more than you are able to walk now?
    - less than I can walk now
    - as much as I can walk now
    - more than I can walk now

19. With your **Custom Made Foot Orthotics** do you expect to be able to do the following activities less or more? If you do not expect any change, choose no change.

- walking inside the house:	□ less	□ more	□ no change
- walking around the garden:	□ less	□ more	□ no change
- housekeeping jobs:	□ less	□ more	□ no change
- shopping for groceries:	□ less	□ more	□ no change
- performing work duties:	□ less	□ more	□ no change
- participating in hobbies:	□ less	□ more	□ no change
- going shopping in town:	□ less	□ more	□ no change
- going for a walk:	□ less	□ more	□ no change
- participating in sport:	□ less	□ more	□ no change

Further questions

20. Are you currently receiving any concurrent/complimentary treatment for your condition?
    - No
    - Yes

    If yes, please select from the list... (Please select all that apply)
    - Physical Therapy
    - Chiropractic
    - Acupuncture
    - Massage Therapy
    - Osteopathy
    - Other: _____

21. Did your Pedorthist suggest any concurrent/complimentary treatment for your condition in addition to using Custom Made Foot Orthotics?
    - No
    - Yes

    If yes, please select the concurrent/complimentary treatment from the list... (Please select all that apply)

- Physical Therapy
- Chiropractic
- Acupuncture
- Massage Therapy
- Osteopathy
- Other: _____

22. What will be the **advantages** of wearing your **Custom Made Foot Orthotics**?

……

23. What will be the **disadvantages** of wearing your **Custom Made Foot Orthotics**?

……

24. Indicate if you expect that the **advantages** will **outweigh** the **disadvantages**.

definitely not ├──────────────────────────────────────┤ certainly yes

25. Are there any other expectations and / or important matters that have not been mentioned in this survey?

……

26. Do you have any final remarks?

……

Thank you for participating in this survey, your feedback is very valuable.

Post-Custom Made Foot Orthotic Use Survey
Administered 6 weeks from the pickup date
Approximately 8 weeks from the assessment date

Background Information

1. How often do you wear your **Custom Made Foot Orthotics**?
   - 6 – 7 days per week
   - 4 – 5 days per week
   - 2 – 3 days per week
   - 1 day per week
   - never (continue with question 4)

2. If you wear your **Custom Made Foot Orthotics**, how many hours a day do you wear them?
   - more than 12 hours
   - 8 – 12 hours
   - 4 – 8 hours
   - 1 – 4 hours
   - less than 1 hour

3. Do you wear your **Custom Made Foot Orthotics** as much as you expected?
   - yes
   - no

4. How satisfied are you with how often you wear your **Custom Made Foot Orthotics**?

Very unsatisfied very satisfied

5. Is your pain or discomfort reduced when you are wearing your **Custom Made Foot Orthotics**?
   - Yes
   - No

6. Does your pain or discomfort return when you are not wearing your **Custom Made Foot Orthotics**?
   - Yes
   - No

7. While wearing your custom foot orthotics, what is your current **maximum walking capacity**? Choose the most appropriate answer.
   - I can walk inside my house (0 – 10 meters)
   - I can walk to the neighbour's house (10 – 50 meters)
   - I can walk to the corner of the street (50 – 200 meters)
   - I can walk to shops etc. in the neighbourhood (200 meters – 1 kilometre)
   - I can walk a fair distance without rest (more than 1 kilometre)

8. **Compared** with the period before you received your **Custom Made Foot Orthotics**, your maximum **walking capacity** …
   - … is improved, because of the **Custom Made Foot Orthotics**
   - … is improved, but not because of the **Custom Made Foot Orthotics**
   - … has not changed
   - … has deteriorated, but not because of the **Custom Made Foot Orthotics**
   - … has deteriorated, because of the **Custom Made Foot Orthotics**

9. Compared with the period before you received your **Custom Made Foot Orthotics**, your **general health** (not specifically your feet) …
   - … has improved
   - … has not changed
   - … has deteriorated

Current situation

10. Indicate the amount of **pain or discomfort** you feel in your feet and / or ankles during activities like standing and / or walking.

None Very much

11. Indicate the location of your **pain** with a cross**.**
    I have no pain radio button.

    Image of Foot and pain location.

Changes due to your Custom Made Foot Orthotics

12. While wearing your **Custom Made Foot Orthotics**, do you have **less or more pain or discomfort** in your feet and / or ankles, during activities like standing and / or walking? Indicate the amount of change in pain.

much less much more

13. While wearing your **Custom Made Foot Orthotics,** please indicate the amount of pain or discomfort **you feel** during the following activities.

- walking inside the house:	**10cm sliding scale from used in question 9 from pre survey.**
- walking around the garden:	**10cm sliding scale from used in question 9 from pre survey.**
- housekeeping jobs:	**10cm sliding scale from used in question 9 from pre survey.**

- shopping for groceries:	**10cm sliding scale from used in question 9 from pre survey.**
- performing work duties:	**10cm sliding scale from used in question 9 from pre survey.**
- participating in hobbies:	**10cm sliding scale from used in question 9 from pre survey.**
- going shopping in town:	**10cm sliding scale from used in question 9 from pre survey.**
- going for a walk:	**10cm sliding scale from used in question 9 from pre survey.**
- participating in sport:	**10cm sliding scale from used in question 9 from pre survey.**

Use of your Custom Made Foot Orthotics

14. Indicate how comfortable your **Custom Made Foot Orthotics feel.**

very uncomfortable ⊢——————————————⊣ very comfortable

15. Indicate if your **Custom Made Foot Orthotics feel worse or feel better** than you **expected**.

⊢——————————⊣

much worse much better

16. Indicate how poor or how well you can **walk** while wearing your **Custom Made Foot Orthotics**.

very poorly ⊢——————————————⊣ very well

17. Indicate if you walk **worse or better** than you **expected** while wearing your **Custom Made Foot Orthotics**.

much worse ⊢——————————————⊣ much better

18. Indicate what you think of the **weight** of your **Custom Made Foot Orthotics**.

Light ⊢——————————————⊣ Heavy

19. Indicate if your **Custom Made Foot Orthotics** are **lighter** or **heavier** than you **expected**.

much lighter ⊢——————————————⊣ much heavier

20. Indicate how difficult it is to **get your custom made foot orthotics in and out of the** footwear your orthotics were intended to be worn in.

Radio button – the orthotics are not removed from their intended footwear.

very difficult very easy

21. While wearing your **Custom Made Foot Orthotics**, do you perform the following activities **less** or **more** than you **expected**?

- walking inside the house:	□ less	□ more	□ no change
- walking around the garden:	□ less	□ more	□ no change
- housekeeping jobs:	□ less	□ more	□ no change
- shopping for groceries:	□ less	□ more	□ no change
- performing work duties:	□ less	□ more	□ no change
- participating in hobbies:	□ less	□ more	□ no change
- going shopping in town:	□ less	□ more	□ no change
- going for a walk:	□ less	□ more	□ no change
- participating in sport:	□ less	□ more	□ no change

Further questions

22. Indicate how well the **Pedorthist** listened to your concerns during your appointments for your **Custom Made Foot Orthotics**?

very poorly very well

23. What are the advantages of your **Custom Made Foot Orthotics**?

……

24. What are the disadvantages of your **Custom Made Foot Orthotics?**

……

25. Indicate whether the advantages outweigh the disadvantages.

definitely not ⊢——————————————————⊣ certainly yes

26. Have your **Custom Made Foot Orthotics** met your goals?
    - yes (if yes, continue with question 28)
    - no (if no, continue with question 27)
    - I do not know (if you do not know, continue with question 28)

27. What is the reason that your goals have not been met?

    ……

28. Describe what you think of the effectiveness of your Custom Made Foot Orthotics in relieving your pain or discomfort?

    ……

29. Describe what you think of the effectiveness of your Custom Made Foot Orthotics in allowing you to increase your activities?

    ……

30. Are there any other features / functions that have not been described which affect the effectiveness of your **Custom Made Foot Orthotics**? Please describe.

    ……

31. Have you in the past six (6) weeks, or are you currently receiving any concurrent/complimentary treatment for your condition?
    - No
    - Yes

    If yes, please select from the list... (Please select all that apply)
    - Physical Therapy
    - Chiropractic
    - Acupuncture
    - Massage Therapy
    - Osteopathy
    - Other: _____

32. Did your Pedorthist suggest any concurrent/complimentary treatment for your condition in addition to using Custom Made Foot Orthotics?
    - No
    - Yes

    If yes, please select the concurrent/complimentary treatment from the list... (Please select all that apply)
    - Physical Therapy
    - Chiropractic
    - Acupuncture

- Massage Therapy
- Osteopathy
- Other: _____

33. How likely are you to recommend Custom Made Foot Orthotics to your family, friends and colleagues?

Very Unlikely Very Likely

34. Why did you answer the way you did in the previous question?
……

Many people have insurance coverage for the costs of **custom made foot orthotics**, either in their extended health benefits, or paramedical health benefits. Some people purchase this extra coverage, or their employer pays for their coverage as part of their employee benefit package. Other people have government assistance for custom made foot orthotics.

35. Based upon this information, the cost of my custom made foot orthotics were…

A: Paid by me or another family member and my costs will be / have been **FULLY** reimbursed by my insurer (covered by extended health benefit, paramedical health benefit coverage etc.).

B: Paid by me or another family member and my costs will be / have been **PARTIALLY** reimbursed by my insurer (covered by extended health benefit, paramedical health benefit coverage etc.).

C: Paid by me or another family member and my costs **WILL NOT BE / WERE NOT** reimbursed by my insurer (not covered by extended health benefits, paramedical health benefits etc.).

D: Paid directly by my insurance coverage (direct billing).

E: Paid directly by me or another family member.

F: Paid directly through government assistance/social services.

G: Other_____

This question is for those people with part/all of the costs of their custom made foot orthotics covered by insurance or government:

36. Would you be willing to pay out of pocket for your custom made foot orthotics, without reimbursement for any costs from your insurer?
- No
- Yes

37. Do you have any final remarks?

……

Thank you for participating in this survey, your feedback is very valuable.

Appendix B – Reported pain by CMFO material

	EVA		Polypro		Suborthelene		XPE		Other	
A	n	%	n	%	n	%	n	%	n	%
1-3	10	91%	89	92%	8	80.0%	4	80%	0	0%
4-7	0	0%	6	6%	2	20%	1	20%	1	100%
8-10	1	9%	2	2%	0	0%	0	0%	0	0%
Total	11	100%	97	100%	10	100%	5	100%	1	100%
B	n	%	n	%	n	%	n	%	n	%
1-3	0	0%	14	14%	0	0%	1	20%	0	0%
4-7	2	18%	33	34%	4	40%	0	0%	1	100%
8-10	9	82%	51	52%	6	60%	4	80%	0	0%
Total	11	100%	98	100%	10	100%	5	100%	1	100%
C	n	%	n	%	n	%	n	%	n	%
1-3	5	83%	35	69%	3	43%	4	100%	0	-
4-7	1	17%	14	27%	3	43%	0	0%	0	-
8-10	0	0%	2	4%	1	14%	0	0%	0	-
Total	6	100%	51	100%	7	100%	4	100%	0	-

A – “When wearing your Custom Made Foot Orthotics, do you expect to have less or more pain or discomfort in your feet and / or ankles, during activities like standing and / or walking? Indicate the amount of change in pain or discomfort you expect.” Results are scored on a 10 point likert scale from ‘much less to much more’.

B – “Indicate how comfortable you expect that your Custom Made Foot Orthotics will feel.” Results are scored on a 10 point likert scale from ‘very uncomfortable to very comfortable’.

C – “Indicate if your Custom Made Foot Orthotics feel worse or feel better than you expected.” Results are scored on a 10 point likert scale from ‘much better to much worse’.