Patient Related Outcome Measures (PROMs) for Foot and Ankle Surgery

Maria Cöster
MD, Foot and Ankle Surgeon
SUS, Malmö
Background

PROMs are important in our clinical practise helping us to evaluate surgery for different types of foot and ankle disorders.
There exist no generally accepted, validated patient-reported score for foot and ankle disorders.
Background

- Since 2006 all patients at the orthopedic department in Kalmar concluded EQ-5D before and 1 year after surgery

- When we summarized our results we found that EQ-5D was not a perfect PROM to use for foot and ankle surgery
Background

• I realized that there was a need for a foot and ankle specific patient-reported score to be used in clinical practice, in research and in a national registry

• At that time “Swedankle”, the Swedish National Ankle Registry, had started to use PROMs
Swedankle

• Since 1993 ankle replacements are included

• Since 2008 also ankle fusions and supramalleolar osteotomies are included

• PROMs have been used in the Registry since 2009; "SEFAS", EQ-5D, SF-36
- SEFAS – Self-reported Foot and Ankle Score
  - patient-reported
  - region-specific
  - based on NZAQ
The New Zealand Ankle Questionnaire (NZAQ)

- This questionnaire was constructed by the New Zealand Arthroplasty Registry for use when evaluating the outcome of total ankle replacement surgery.
- The score is based on the validated Oxford-12 score for hip.
- 12 questions – each with 5 responses.
- The NZAQ was not validated.
• In 2009 The New Zealand Ankle Questionnaire (NZAQ) was translated and cross-cultural adapted to Swedish conditions and implemented in “Swedankle”

• **SEFAS** is the Swedish version of the score
1. How would you describe the pain you usually have from the ankle in question?

1 □ None
2 □ Very mild
3 □ Mild
4 □ Moderate
5 □ Severe

4. Have you had to use an orthotic (shoe insert), heel lift or special shoes?

1 □ Never
2 □ Occasionally
3 □ Often
4 □ Most of the time
5 □ Always
• 2010 we started to evaluate the psychometric properties of the SEFAS (M Cöster, Å Carlsson, M Karlsson)

• We included patients registered in the Swedankle with osteoarthritis or inflammatory arthritis in the ankle
Study 1

- 74 women and 61 men (aged 26 to 85)
- All patients completed two ankle-specific and two general scores
  - SEFAS
  - FAOS
  - SF-36
  - EQ-5D
FAOS

• Foot and Ankle Outcome score
• A patient-reported ankle score available in Swedish
• Validated in patients with ankle instability, (acquired flatfoot and hallux valgus)
• 42 questions- too long to be ideal in a registry
Method

The validation process was done according to international guidelines.

- Construct validity
- Floor and ceiling effects
- Test-retest reliability
- Internal consistency
- Responsiveness
Results

- The Construct validity analysis for SEFAS showed both strong and weak correlations as we had hypothesized when we compared SEFAS to SF-36 and the other scores.
- SEFAS had:
  - no floor and ceiling effects
  - good test-retest reliability
  - good internal consistency
  - good responsiveness

Study 2

• The next step was to evaluate the SEFAS also in patients with different disorders in the forefoot, the hindfoot or the ankle

• We included patients planned for surgery in the orthopedic departments in Kalmar and Eksjö
Study 2

- 96 women and 22 men (aged 16 to 87) with disorders in the forefoot

- 59 women and 47 men (aged 18 to 81) with disorders in the hindfoot or ankle

- All patients completed SEFAS, FAOS, SF-36 and EQ-5D before surgery and 6, 12 and 24 months after surgery
Results

• We found like in our first study acceptable/good psychometric properties for SEFAS in terms of validity, reliability and responsiveness

• The American orthopedic foot and ankle society score (AOFAS) is for many foot and ankle surgeons the gold standard for evaluation of foot and ankle disorders

• Even if AOFAS is partial examiner-dependent requiring a clinical examination, we wanted to compare the psychometric properties for AOFAS and SEFAS
Study 3

We included for this comparison patients planned for surgery in the orthopedic departments in Kalmar and Eksjö.
Study 3

- 80 women and 15 men (aged 18 to 78) with disorders in the hallux

- 62 women och 49 men (aged 24 to 81) with disorders in the hindfoot or the ankle

- SEFAS and AOFAS were completed before and 6 months after surgery
Results

- We found a strong correlation between SEFAS and AOFAS
- Both scores had good responsiveness and no floor or ceiling effects.
- The reliability tests were better for SEFAS than for AOFAS
- AOFAS took more time to conclude

Cöster MC, Rosengren B, Karlsson M, et.al. Comparison of the Self–Reported Foot and Ankle Score (SEFAS) and the American Orthopedic Foot and Ankle Society Score (AOFAS). Foot Ankle Int.2014; Jul 11. pii: 1071100714543647. [Epub ahead of print]
• 2013 a Rasch-analysis of the SEFAS was conducted

• Results from this analysis will not be presented here

• The next step is to validate the Rasch analyzed score
What happens now?
We are now ready to start up a nationwide registry for all types of foot and ankle surgery as an addition to Swedankle.

The plan is to start in March 2015.

RIKSFOT is the Swedish name of the registry.
Swefoot/Swedankle

- During 2016 we plan to merge the two registries

- SEFAS will be used as a PROM in both registries

- The first results from Swedankle with PROMs concerning revision-TARs will hopefully be published next year
Thank you!