FACULTE DE MÉDECINE ET DES SCIENCES DE LA SANTÉ — École de réadaptation — Sherbrooke, Québec, Canada

Efficacy of a Vacuum Removable Rigid Dressing After a Trans-Tibial Amputation: A Pilot Study Research Protocol

Frank Néron-Larocque[1], Vincent Bernard-Larocque[1], Danik Schinck[1], Francis Binette[1], Jean-Sébastien Boulay[1], Michel Tousignant[1, 2], pht, Ph.D., Ariane Rajotte Martel[3], MD

[1] Faculté de Médecine et des Sciences de la Santé, Université de Sherbrooke, Quebec, Canada
[2]Research Center on Aging, Université de Sherbrooke, Quebec, Canada
[3]CHU de Québec – Université Laval, Quebec, Canada

Background

- Between 1996 and 2004, around **4000 trans-tibial amputations** occurred in Quebec.[1]
- A tibial amputee will spend on average **51 days** in different healthcare institutions.[2] Following release from hospital care, patients spend an **additional 8 to 10 weeks** in out-patient or in-care rehabilitation before final release from rehabilitation.[3]
- The determining factor for time of prosthetic fitting is the **stability of stump size** which varies according to oedema.[4]
- Some dressings used as compression modalities are the **elastic dressing (ED)** (recommendation level: **not recommended**) and the **removable rigid dressing (RRD)** (recommendation level: **B**).[5]
- **The RRD has a lower risk of infection** compared to the rigid dressing because it can be removed to verify stump daily.[6]
- Despite its superior efficiency, the RRD remains a modality that is **not commonly used in Canada**, particularly in Quebec.[3]

Problematic

- Currently, the **ED is a commonly used compression modality**, despite it being **not recommended** by literature.[5]

Objectives

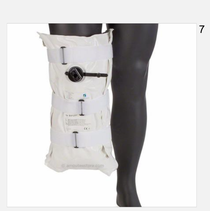
- To provide an estimate on the **efficacy of the Ossür Rigid Dressing (ORD)**, which is an RRD-type dressing, **compared to the ED.**

Secondary objectives

- Assess **facilitators and barriers** to ORD implantation as a post-tibial amputation dressing modality, compared to the ED.

Independant variables

- ORD or ED as a post-amputation compression modality to stabilize oedema.



[7]

Main outcome measure

- **Time** to preliminary prosthetic fitting.

Secondary outcome measures

- Stabilisation of stump size (oedema);
- Complications (stump infection, pressure ulcers).

Inclusion criteria

1. Trans-tibial amputation secondary to atraumatic causes;
2. Between 40-75 years of age;
3. Able to give enlightened consent.

Sample

This research aims to assess the efficacy of both modalities on 20 trans-tibial amputees total (10 with ORD, 10 with ED).

Methods

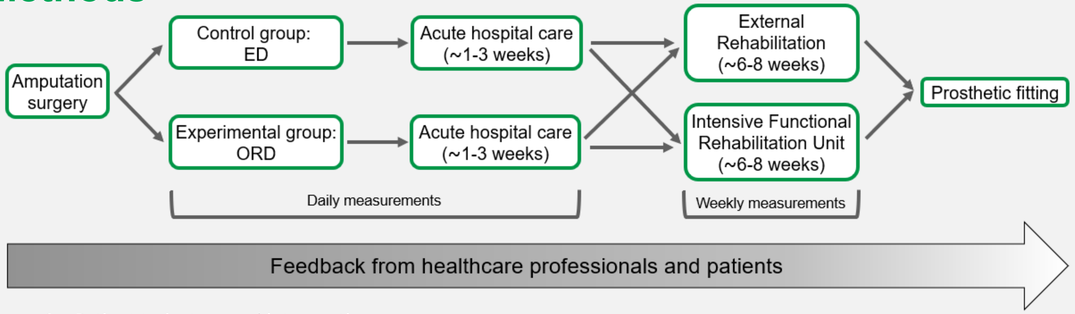


Figure 1 – Patient trajectory and interventions.

Developments

Coordination with multiple collaborators to assure health care services continuum

- Vascular surgeons (recruitment, initial application of ORD or elastic dressing)
- Physical therapy professionals (measurements, in-/outpatient rehabilitation)
- Nursing staff (wound treatment)

Ethics and scientific approval: March 2018

Revision of inclusion/exclusion criteria

Inclusion criteria
1. Trans-tibial amputation secondary to atraumatic causes;
2. Between 40-75 years of age;
3. Able to give enlightened consent.

Exclusion criteria
1. Medical condition that can affect healing significantly;
2. Inability to collaborate in the rehabilitation protocol.

Multicenter study
CHU de Québec – Université Laval

- Dre Arianne Rajotte-Martel, MD (physiatrist)
- Dr Ghislain Nourissat, MD (vascular surgeon)
- Ethics and scientific approval: March 2019

What awaits us

- Recruitment of the first patient.
- Waiting for institutional approval for the CHU de Québec – Université Laval site.
- Presentation of our research project by Guylaine Nadeau, CRC, at a CSVN congress on September 11th and 12th 2019, in Kelowna, British Columbia, Canada.

Figure 2 – Project development thus far.

Projections

Precursor to a **larger multicentric study** in collaboration with the CHU de Québec – Université Laval.

Our predictions:

- Reduced **time to preliminary prosthetic fitting** with ORD.
- Reduced risk of **complications** following surgery with ORD given that the dressing is easily removable.
- Shorter duration of **acute hospital care** with ORD.
- Decreased **rehabilitation time** required between amputation and prosthesis fitting.

Reduction in **healthcare costs**:

- Average trans-tibial amputee costs 82 000 $USD the **first year** following amputation.[8]
- Considering that **acute hospital care** costs ~38 000 $USD.[8]
- Patient **rehabilitation** costs ~6 500 $USD.[8]
- Physician/**outpatient care** costs ~19 000 $USD.[8]

Conclusion

Considering the ORD could potentially **reduce complications and rehabilitation time** to prosthetic fitting, it could lead to an **important reduction in medical and rehabilitation costs** for trans-tibial amputees.

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