Clinical Assessment of An External Neck Brace to Support the peristomal Fixation of an Automatic Stoma Valve (ASV) in laryngectomized patients using hands-free speech: 3D stereophotogrammetrical assessment.

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Peristomal fixation problems after total laryngectomy of adhesives and stoma valves are still main reasons accounting for the relatively small amount of patients that actually use an automatic stoma valve on a daily basis. Several concepts could not...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON32779

Source
ToetsingOnline

Brief title
Neck Brace supported fixation of an automatic stoma valve

Condition

- Other condition

Synonym
spraakverbetering bij gelaryngectomeerden, trachoesophageale speech rehabilitation

Health condition

Post operatieve spraak rehabilitatie bij gelaryngectomeerden

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Intern budget

Intervention

Keyword: 3D stereophotogrammetry, automatic stoma valve, external neck brace, peristomal fixation

Outcome measures

Primary outcome

Benefit of the external neck brace related to peristomal fixation of adhesives

and the reduction of air leakage and the amount of adhesives used per day.

Secondary outcome

Correlation between tracheostoma anatomy and peristomal fixation of adhesives.

Study description

Background summary

The gold standard for voice restoration after total laryngectomy is still the use of a unidirectional shunt valve creating tracheoesophageal speech . Hands-free speech is the ultimate goal to strive for, since many patients find digital stoma occlusion uncomfortable because this draws attention to their handicap and occupies one hand during speech. The introduction of automatic stoma valves (ASV) was promising at first but according to the literature only serves approximately 30% of all laryngectomees. In daily practice this number seems to be overestimated.
The relatively low success rate of ASVs can be partially explained because of peristomal fixation problems. High backpressure needed for voicing and unstable fixation cause the ASV to detach. It is generally accepted that differences in individual tracheostoma anatomy play a large role in peristomal fixation problems. These anatomical differences were assessed in an earlier study using

a 3D stereophotogrammetrical imaging technique. This promising method not only turned out to be an excellent tool for the measurement of several stoma parameters such as circumference, depth, surface size and diameters, but also facilitates calculation of absolute mean differences between two pictures of different conditions.
Several concepts were tried to overcome fixation problems. However, stronger glues and the introduction of different types of adhesives still could not prevent adhesive loosening or air-leakage and sometimes even led to progressive skin irritation.
In order to overcome or at least diminish these attachment problems, an external neck brace (ENB) has been developed to support peristomal adhesives. The mechanism behind this brace is that it absorbs the high pressures created during tracheoesophageal speech.

Study objective

Peristomal fixation problems after total laryngectomy of adhesives and stoma valves are still main reasons accounting for the relatively small amount of patients that actually use an automatic stoma valve on a daily basis. Several concepts could not prevent these fixation problems. In order to overcome or at least diminish these attachment problems, an external neck brace (ENB) has been developed to support peristomal adhesives. The mechanism behind this brace is that it absorbs the high stomal pressures created during tracheoesophageal speech. Clinical assessment will show the extent and amount of laryngectomized patients that will actually benefit from supported peristomal fixation with an external neck brace.

Study design

Prospective clinical pilot study in a University Hospital setting (UMC St Radboud).

Study burden and risks

not applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy laryngectomized patients with a minimum time of 6 months post operative. Voice prosthesis users that use tracheoesophageal speech.

Exclusion criteria

Patients that are ill, unmotivated, not able to use the adhesives / external neck brace provided. Allergic reactions to the adhesives provided

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-02-2010
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	23-02-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL31182.091.09