ISRCTN04247943 https://doi.org/10.1186/ISRCTN04247943

Nitrogen balance after prosthetic rehabilitation of complete edentulous patients with fixed prosthesis or implant retained overdenture

Submission date
20/02/2012

Recruitment status
No longer recruiting

Registration date
30/03/2012

Overall study status
Completed

Last Edited
26/05/2017

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients who wear conventional dentures (false teeth) may have chewing difficulties if the dentures don't fit properly, which may affect their desire and ability to eat. This can lead to an unbalanced diet and low nutrient intake. Studies have shown that the ability of patients with dentures to chew improves when the lower denture is fully or partly supported by endosseous implants - surgical components that interface with the bone of the jaw. The aim of this study was to assess the impact of implant-supported overdentures on chewing and nutrition.

Who can participate?
Patients aged 54-79 who wear conventional dentures

What does the study involve?
Participants are randomly allocated to wear either implant-supported overdentures or conventional dentures. Their diet is assessed and urine samples are collected in a special container over a 24-hour period to measure their protein intake.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Free Center of Dentistry (Brazil)

When is the study starting and how long is it expected to run for?
January 2011 to December 2011

Who is funding the study?
Free Center of Dentistry (Brazil)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
A randomised controlled trial comparing nitrogen balance after prosthetic rehabilitation of complete edentulous patients with fixed prosthesis or implant retained overdenture

Study objectives
Complete edentulous patients wearing conventional dentures generally show chewing difficulties due to ill-fitting dentures may profoundly influence ones desire and ability to eat properly. It has been suggested that these factors can lead to an unbalanced diet and deficient nutrient intake. Studies have shown that the ability of edentulous patients to chew most foods improves significantly when the mandibular denture is fully or partly supported by endosseous implants. Complete denture wearers have been shown to have significant differences in nitrogen intake when compared to patients that received implant-supported overdenture.

The purpose of the current study was to clarify the objective impact of implant-supported overdentures on mastigatory performance, nutritional state and nutritional habits. The research questions evaluated were:
1. Whether implant supported overdentures provide greater improvement in mastigatory performance compared to conventional dentures
2. If implant supported overdentures impact food selection
3. Whether implant supported overdentures provide higher protein intake and improved protein utilization
Nitrogen Balance (NB) is an important calculation for assessing nutritional response and it is used to evaluate the adequacy of protein intake as well as to estimate current protein requirements.

The results showed that stability of the mandibular implant-retained overdenture was enhanced compared to a conventional denture as well as the quality of life and satisfaction levels. Seventy-five percent of patients changed their nutritional pattern, has been evidenced by the 24-hour dietary test. This change led to a substantial increase in protein intake and, as a consequence, to a improved nitrogen balance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethics approval was not sought because it is a verification of the efficiency of removable prosthesis implant. This is not an experimental study.

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prosthodontics

Interventions
Subjects received either implant-supported denture (ISD) or tissue-implant-supported denture (TISD)

The 24-hour dietary recall method was selected to measure dietary intake of the patients in the current survey. This was based on a review of the literature, which has used the 24-H- RQ method. Twenty-four hour urine collection was performed in order to estimate protein metabolism by collecting a person's urine in a special container over a 24-hour period.

Evaluation of protein metabolism
There was no change in the treatment and diet of patients during the course of the study. On the test day, in the morning at the commencement of collection period (6.00 a.m.) patients were asked to void urine and discard this sample (as it contains the overnight urine present in the bladder). Subsequently urine was collected for next 24 hrs. The last sample was to be collected on next day at 6.00 a.m. A random sample was also collected at around 11.0 a.m. on the day of deposition of 24 hr sample (the test day).

Nitrogen balance trial
Nitrogen excretion is determined by certain factors, mainly crude protein content of diet. Nitrogen balance trials are not only used to determine amino acid requirement, but also for the best amino acid ratio (Hahn and Baker, 1995). A nitrogen balance trial was carried out with 4 patients. The values of nitrogen intake (NI), output in feces (NOF) and in urine (NOU) were calculated by multiplying nitrogen levels of diets, feces and urine, by feed intake, excreted feces and urine, respectively. Nitrogen absorption (NAB = NI NOF), total output (TNO = NOF + NOU), retention (NR = NI - TNO), net protein utilization (NPU = NR/NI) and the biologic value of feed

protein (BVFP = NR/NAB) were subsequently calculated. The values of nitrogen intake (NI), output in feces (NOF) and in urine (NOU) and UUN are the nitrogen production during the 24-hour period.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Nitrogen Balance (NB) for assessing nutritional response and to evaluate the adequacy of protein intake as well as to estimate current protein requirements

Key secondary outcome(s)
1. Patient overall satisfaction: Was significantly higher for the mandibular overdenture. In addition, mandibular overdenture patients were significantly more satisfied with chewing experience and retention of the lower denture. conversion from a lower conventional complete denture to an implant-retained overdenture increased retention of the prosthesis
2. Improvement in masticatory performance
3. Protein ingestion: limited effect has been observed

Completion date
01/12/2011

Eligibility

Key inclusion criteria
1. Aged 54-79
2. Bimaxillary edentulous patients wearing conventional dentures and without deglutition problems
3. Informed written consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
Sera of patients with compromised metabolic health with chronic diseases

Date of first enrolment
01/01/2011

Date of final enrolment
01/12/2011

Locations

Countries of recruitment
Brazil

Study participating centre
Rua Barão de Flamengo 22
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Sponsor information

Organisation
Free Center of Dentistry (Brazil)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Free Center of Dentistry (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration