

Trial Description

Title

CT database for evaluation of automatic image segmentation programs in the maxillofacial area

Trial Acronym

enFacedDB

URL of the trial

[---]*

Brief Summary in Lay Language

Computer- assisted technologies such as image- based segmentation play an important role in the diagnosis and treatment support in oral- and maxillofacial surgery. However, although many image- based segmentation approaches exist, their clinical in- house use is often strongly limited due to technical, human or financial resources. Especially in open- source based segmentation, systematic evaluations of segmentation approaches are lacking. Therefore, the aim of this study is to assess the real segmentation quality of commonly available and license- free segmentation programs in the maxillofacial area. The assessment is done in a comparison between segmented CT- image data of the maxillofacial area. Segmented patient- specific clinical image data performed by automatic segmentation algorithms are compared with the manual ground truth segmentations performed by clinical experts. Assessment parameters are amongst others the Dice Score Coefficient (DSC, %) and the Hausdorff Distance (HD, voxel). This study is a systematic comparison that evaluates multiple license- free, open- source segmentation programs and software platforms in the maxillofacial area based on clinical CT- data for the improvement of segmentation algorithms and a potential clinical use in patient- individualized medicine in the field of oral and maxillofacial surgery. Further, the results presented are reproducible by others and can be used for both clinical and research purposes.

Brief Summary in Scientific Language

Computer- assisted technologies such as image- based segmentation play an important in the diagnosis and treatment support in oral- and maxillofacial surgery. However, although many image- based segmentation approaches exist, their clinical in- house use is often strongly limited due to technical, human or financial resources. Especially in open- source based segmentation, systematic evaluations of segmentation approaches are lacking. Therefore, the aim of this study is to assess the real segmentation quality of commonly available and license- free segmentation programs in the maxillofacial area. The assessment is done in a comparison between segmented CT- image data of the maxillofacial area. Segmented patient- specific clinical image data performed by automatic segmentation algorithms are compared with the manual ground truth segmentations performed by clinical experts. Assessment parameters are amongst others the Dice Score Coefficient (DSC, %) and the Hausdorff Distance

(HD, voxel).

This study is a systematic comparison that evaluates multiple license- free, open-source segmentation programs and software platforms in the maxillofacial area based on clinical CT- data for the improvement of segmentation algorithms and a potential clinical use in patient-individualized medicine in the field of oral and maxillofacial surgery. Further, the results presented are reproducible by others and can be used for both clinical and research purposes.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00014853**
- Date of Registration in DRKS: **2018/06/29**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **30-340 ex 17/18 , Ethikkommission der Medizinischen Universität Graz**

Secondary IDs

Health condition or Problem studied

- ICD10: **S02 - Fracture of skull and facial bones**
- ICD10: **M85 - Other disorders of bone density and structure**
- ICD10: **Q75 - Other congenital malformations of skull and face bones**
- ICD10: **S09 - Other and unspecified injuries of head**
- ICD10: **K10 - Other diseases of jaws**
- ICD10: **K07 - Dentofacial anomalies [including malocclusion]**
- ICD10: **Z96 - Presence of other functional implants**

Interventions/Observational Groups

- Arm 1: **Establishment of a CT database (CT, PET/CT etc.) of the maxillofacial area with datasets from the clinical routine for the comparative evaluation of multiple image- based computer programs and platforms.**
- Arm 2: **Automatic maxillofacial bone segmentation with computer programs on CT data (CT,PET/CT etc.) basis: time of measurement (T) with Hausdorff Distance (HD, voxel)/ Dice Similarity Score (DSC, %)/ Volume (V, mm³)/ Voxel (Vx, Number)/Time (t, min., sec.) as well as 3D printing of facial models and evaluation of Augmented Reality Systems on CT data basis.**
- Arm 3: **Manual maxillofacial bone segmentation by clinical experts (Ground Truth) on CT data basis: time of measurement (T) with Hausdorff Distance (HD, voxel)/ Dice Similarity Score (DSC, %)/ Volume (V, mm³)/ Voxel (Vx, Number)/ Time (t, min., sec.)**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Basic research/physiological study**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Comparison image based segmentation of maxillofacial CT- data between automatic (algorithm) vs. manual (clinical experts) at measurement point T by Hausdorff Distance (HD, voxel) and Dice Similarity Score (DSC, %).

Secondary Outcome

Comparison image based segmentation of maxillofacial CT- data between automatic (algorithm) vs. manual (clinical experts) at measurement point T by Volume (V, mm³), Voxel (Vx, Number), time (t, min., sec.).

Countries of recruitment

- AT **Austria**

Locations of Recruitment

- University Medical Center **Medizinische Universität Graz, Graz**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/08/01**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **99 Years**

Additional Inclusion Criteria

Physiologically functional, complete maxillofacial bones

Exclusion criteria

- **Implants or osteosynthesis material**
- **Age <18 Years**
- **Bone necrosis or pathologic-cystic changes of the bones**

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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■ **Collaborator, Other Address**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

FWF

Sensengasse 1

1090 Wien

Austria

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Austrian Science Fund (FWF) KLI 678-B31: “enFaced: Virtual and Augmented Reality Training and Navigation Module for 3D-Printed Facial Defect Reconstructions” (PIs: Jürgen Wallner and Jan Egger)
1090 Wien

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URL: [---]*

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.