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Computer-Assisted Surgical Planning for Soft Tissue Reconstruction of Complex Head and Neck Defects

The anatomy of the head and neck is extremely complex, and oftentimes soft tissue reconstruction is compromised by the use of free flaps that use simple shapes (e.g. rectangle or ellipse) to reconstruct complex anatomical defects. This could result in worse deformity and/or function than a free flap that is tailored in shape to fit the specific defect. There are numerous challenges that hinder the precise shaping of flaps in clinical practice, however the ability to predict and model the defect in a virtual environment may help circumvent many of these barriers. The goal of this study is to demonstrate the feasibility of "virtual surgery" for planning the reconstruction of complex soft tissue defects of the head and neck. This proof-of-concept study does not involve any intervention or interaction with subjects and uses only de-identified imaging and clinical data. Our purpose is to demonstrate the feasibility of computer planning for soft tissue free flap surgery, which presents unique challenges compared with bone reconstruction. All study procedures are performed outside of the clinical setting, principally using three-dimensional computer modeling software. The anticipated end result of the study is the successful creation of "templates," either virtual models or 3D printed templates, which could theoretically be used to perform soft tissue free flap surgery. Should this goal be obtained, it could lead to clinical studies to determine if computer-assisted planning can be utilized to produce more faithful reconstructions with respect to normal anatomical contours.

Data obtained for this study will include: 1) De-identified DICOM data from imaging studies, such as CT, MRI, and PET/CT, and 2) limited demographic and clinical information such as age, gender, diagnosis, and clinical exam findings. The imaging data will be manipulated in silico using three-dimensional (3D) modeling software such as Autodesk MAYA 2022 or related open source software (3D-Slicer, Meshmixer, Blender). A subject's deidentified CT, MRI, and/or PET/CT data will be converted to an STL file for digital manipulation within the software. Due to the challenges in reliably delineating / modeling the complex anatomy of the mouth and throat on imaging studies, a generic digital model of the mouth and throat (obtained from turbosquid.com) will be fused with the patient-derived data to create a hybrid model that represents the specific dimensions of the patient's anatomy, while resulting in a more "cartoonish" representation of these anatomic regions – this will facilitate conceptualization of the digital surgery and reconstruction. The site of the pathology (e.g. tumor) and the anticipated defect that would result from its resection will be marked out on the fused 3D representation of the subject's anatomy in silico. The region encompassing the "virtual resection" will be cropped, thus creating a virtual 3D model of the defect. This 3D model will be manipulated within the software to create a two-dimensional template that takes into account areas of folding or trimming of a soft tissue free flap that would be necessary to recreate the anatomical defect in three-dimensions.

Inclusion criteria will be any subject with a condition that, when treated surgically, would result in a soft tissue defect that is determined by the PI to be "complex", including through-and-through defects extending from the mouth or throat to the external skin; defects

involving the soft palate or lips; defects involving any two of the following: tongue, floor of mouth, oropharynx, buccal mucosa, hard palate, and gingiva of the maxilla or mandible.