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Systematic Review
Orthognathic Surgery

Three-dimensional cone beam computed tomography analysis protocols for condylar remodelling following orthognathic surgery: a systematic review

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Abstract. Orthognathic surgery involving the mandible can lead to remodelling of the temporomandibular joint (TMJ). Cone beam computed tomography (CBCT) provides an easily accessible three-dimensional (3D) approach to study this entity. A systematic review of the literature was performed with the aim of identifying condylar remodelling analysis protocols using CBCT-derived 3D models. The search yielded 10 eligible studies. The systematic review identified three pillars of a condylar remodelling analysis protocol that were retrievable from each of the included studies: (1) registration, (2) segmentation, and (3) analysis. The studies lacked consensus on how these pillars should be transferred to their respective protocol. Through critical assessment, criteria for a universal condylar remodelling analysis are suggested: (1) performance of a regional voxel-based registration of baseline and postoperative CBCT scans using an anatomical region not prone to postoperative changes, (2) application of a (semi-)automated 3D segmentation algorithm, (3) performance of a combination of both volumetric and surface-based 3D condylar analysis, and (4) extensive validation of each step of the protocol. The homogenization of condylar remodelling analysis protocols and their incorporation into virtual planning software suites raises the potential for the inclusion of larger numbers of patients in future prospective studies in order to gain evidence-based data.

Key words: orthognathic surgery; condylar remodelling; cone beam computed tomography; three-dimensional analysis.

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Orthognathic surgery can induce structural changes to the temporomandibular joint (TMJ)[1,2]. Intraoperative and postoperative forces such as the mandibular split, mobilization of the proximal segment, condylar torque, an altered postoperative condylar position, and soft tissue tension exert their effects on the TMJ[3]. These can all culminate in a remodelling process altering the shape of the condyle. Condylar remodelling can be either pathological or physiological[4]. Physiological condylar remodelling occurs in most operated patients without causing clinical symptoms. However, if the adaptive capacity of the remodelling is surpassed, pathological remodelling and related clinical symptoms may follow. Degenerative joint disease and condylar resorption are two feared pathological remodelling outcomes[5–7].

Cone beam computed tomography (CBCT) provides a three-dimensional (3D) approach, without overlap of the anatomical structures and with high resolution, to study the TMJ where conventional radiographs lack the accuracy to detect remodelling[8,9]. Nowadays, CBCT is an essential part of the orthognathic work-up and follow-up. The preoperative data are used for 3D virtual surgical planning and the postoperative data can be utilized to study the accuracy of the transfer, postoperative remodelling, and stability[10,11]. The advantages of vertical CBCT scanning in contrast to conventional computed tomography (CT) are the lower radiation dose, lower cost, and the possibility to scan patients in natural head position[12].

The true nature of 3D information lies in segmenting the desired volume out of the CBCT data and comparing 3D models[13]. By segmentation of the bony joint structures and applying rigid registration of follow-up CBCT scans, a detailed evaluation of condylar remodelling can be performed. These data can be combined with skeletal stability analysis and clinical patient symptoms to further investigate degenerative joint diseases following orthognathic surgery.

With the emerging availability of 3D-CBCT follow-up data for orthognathic patients, multiple condylar remodelling analysis protocols have been reported. However, researchers are using different CBCT protocols, image parameters, software packages, segmentation and registration protocols, and analysis techniques. This may lead to a wide variety of study protocols, all having their strengths and weaknesses. The goal of this systematic review was to identify condylar remodelling analysis protocols using CBCT-derived 3D models. These protocols were then critically assessed in order to formulate criteria for the development of an accurate condylar remodelling analysis protocol with a low risk of operator error

Methods

Objective

To identify and assess methods for the evaluation of condylar remodelling following orthognathic surgery using 3D models derived from CBCT data.

Protocol

A systematic review of the available literature was performed using the guidelines of the PRISMA statement (Preferred Reporting Items for Systematic Reviews and Meta-Analyses)[14]. This study was registered with the International Prospective Register of Systematic Reviews (PROSPERO) with identification number CRD42018092939.

Information sources

A literature search was conducted using the electronic databases PubMed (National Library of Medicine, NCBI), Cochrane Central Register of Controlled Trials, Web of Science, and Embase in order to identify relevant studies published up until April 2018.

Search strategy

A search strategy was developed for the four databases that combined search terms within three concepts. Concept 1 consisted of terms related to orthognathic surgery, concept 2 handled terms related to the TMJ, and concept 3 included terms related to CBCT. The terms for each concept were joined using the Boolean operator 'OR'. The concepts themselves were joined using the Boolean operator 'AND'. The search terms were a combination of controlled vocabulary (MeSH or Emtree) and free text terms. The full search protocol for the different databases is given in the **Supplementary Material** (Table S1). No language or date restrictions were applied. The grey literature was not searched.

Selection of studies

All identified studies were loaded into the online Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia; www.covidence.org) for screening and data extraction. After the removal of duplicates, all titles and abstracts were screened by two reviewers. Next, all full texts of the relevant articles were reviewed by the same reviewers to determine whether they fulfilled the inclusion criteria. The title and abstract screening as well as the full text reviewing were performed independently by the two reviewers. At the end of each stage, disagreements were resolved through discussion and consensus. If no consensus could be reached, a third party was asked to review the study.

Eligibility criteria

Eligibility criteria were set a priori using the PICOS participant–intervention–comparison–outcome–study design scheme. Eligibility criteria are presented in Table 1.

Data extraction and management process

The data extraction from all studies was performed independently by two

Table 1. Eligibility criteria for the studies.

Inclusion criteria
Participants (P)
Human patients of all ages and any sex
Non-syndromic dentofacial deformity
Intervention (I)
Orthognathic surgery
Pre- and postoperative follow-up CBCT scans
Comparison (C)
Studies assessing condylar remodelling using 3D models derived from follow-up CBCT scans of at least 6 months
Outcomes (O)
Condylar remodelling analysis protocols based on 3D models derived from CBCT data
Types of study (S)
Clinical trials, cohort studies, case–control studies, cross-sectional studies
Prospective and retrospective studies with a minimum follow-up of 6 months
Exclusion criteria
Syndromic patients
Sole genioplasty procedures
CT-derived 3D models for the evaluation of condylar remodelling
Condylar remodelling analysis not using 3D models
Animal studies, ex vivo research, or single case reports

3D, three-dimensional; CBCT, cone beam computed tomography; CT, computed tomography.

reviewers. Forms were developed to allow for a universal means of data extraction. After individual data extraction, the forms were reviewed by the two authors and a final form was constructed.

Methodological quality assessment

Assessment of the methodological quality of the studies was performed using the Methodological Index for Non-Randomized Studies (MINORS)[15]. This scoring system evaluates eight domains for non-comparative studies and 12 domains for comparative studies. A domain is scored as '0' when not reported, '1' if it is inadequately reported, and '2' when it is adequately reported. Ideal scores are respectively 16 for non-comparative studies and 24 for comparative studies. The higher the score, the lower is the risk of bias of the study. The scoring was performed independently by two reviewers. Conflicts were resolved through discussion.

Results

Selection of studies

The screening and selection process is shown in Fig. 1. The search yielded a total of 2924 studies. After the removal of duplicates, 1843 studies were screened by title and abstract, of which 82 were deemed relevant and were assessed for eligibility. Eventually, 10 studies were included in the qualitative synthesis (Table 2)[16–25]. Every included study investigated condylar remodelling using 3D models, although the main study objective differed among the studies. Five studies focused on the relationship between skeletal stability and condylar remodelling after orthognathic surgery[16,18,19,21,24], two on the effect of proximal segment rotation and condylar remodelling[20,22], two on the effect of orthognathic surgery and simultaneous disc repositioning on condylar remodelling[17,23], and one study investigated solely the phenomenon of condylar remodelling following orthognathic surgery[25]. The studies were published between 2010 and 2018 and used 3D models derived from segmentation of the CBCT DICOM data to evaluate condylar remodelling.

The results of the methodological quality assessment are presented in Table 2. All studies had a moderate risk of bias.

Patients

Combining all studies, 421 patients were included, of whom 134 were male and 287 were female. Eighty patients had a class III dentofacial deformity. Of these patients, 40 had bimaxillary surgery, 25 had a Le Fort advancement procedure and 25 had a sole BSSO setback procedure. The remaining 341 patients had a class II deformity. They were treated with bimaxillary surgery ($n = 117$), bimaxillary surgery with simultaneous disc repositioning ($n = 58$), or BSSO advancement ($n = 166$) (Table 3).

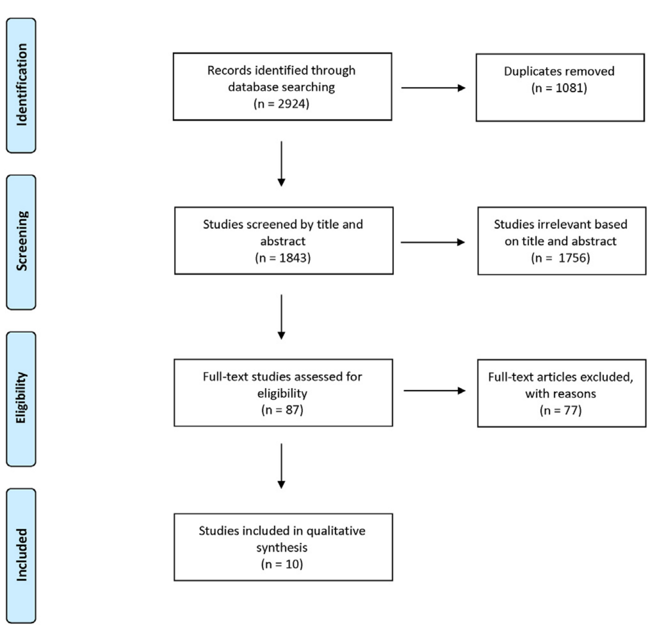

Fig. 1. Overview of the selection process according to the PRISMA guidelines.

Image acquisition

CBCT scans were taken preoperatively in every study. The timing of the follow-up CBCT scans used for studying condylar remodelling differed among studies and is reported as remodelling time frame in Table 4. All patients had a minimum follow-up of at least 6 months. The field of view applied in the studies was described as 22 × 16 cm (four studies), 12-inch (three studies), 23 × 17 cm (two studies), or 20 × 19 cm (one study). CBCT scan times ranged from 17.8 seconds to 40 seconds. Voxel sizes ranged from 0.3 mm^3 to 0.5 mm^3. Only three studies stated that patients were scanned in centric relation using a wax bite[16,18,19]. Two other studies mentioned that the patients were manually guided into centric relation just before taking the scan, without a wax bite[17,24]. One study stated that patients were scanned in maximum intercuspation[20] and the remaining four studies did not specify the occlusion during scanning.

Registration protocols (Table 4)

Rigid registration techniques were used in seven studies for the analysis of condylar remodelling[16–20,23,24]. The technique superimposes follow-up CBCT scans of a patient to evaluate changes over time in specific regions. This technique can be subdivided into voxel-based, surface-based, and point-based registration.

Voxel-based registration uses voxel grey-scale values to match identical voxels of two scans[26]. A volume of interest (VOI), i.e. the cranial base, is selected and an algorithm will match and transform all voxels of the VOI of the follow-up scan to the location of the original scan. All voxels of the follow-up scan will then move according to the transformation of the voxels of the VOI. Five studies opted for voxel-based registration to evaluate condylar remodelling. Four studies used the cranial base as the VOI[16–19] and one study chose the condyle itself as the VOI[23].

Surface-based registration uses the surface of the segmentation-derived 3D models[26]. An algorithm tries to match two given surfaces of a chosen region of interest to obtain a uniform overlap of these surfaces. Two studies used mandibular structures such as the condylar neck, sigmoid notch, or posterior border of the ramus to superimpose the mandible and then evaluate condylar remodelling[20,24].

Three studies skipped registration techniques for condylar remodelling analysis[21,22,25]. Two of them did perform rigid registration for other reasons[21,22]. Point-based registration was not performed in the included studies.

Table 2. Overview of the included studies, study goals, and assessment of bias.

Author (Year)	Title	Study goal	Bias assessment (MINORS[a])
Carvalho et al. (2010)[16]	Three-dimensional assessment of mandibular advancement 1 year after surgery	Evaluate condylar remodelling and skeletal stability following orthognathic surgery	11/16
Goncalves et al. (2013)[17]	Temporomandibular joint condylar changes following maxillomandibular advancement and articular disc repositioning	Evaluate the effect of orthognathic surgery with and without disc repositioning on condylar remodelling	16/24
de Paula et al. (2013)[18]	One-year assessment of surgical outcomes in class III patients using cone beam computed tomography	Evaluate condylar remodelling and skeletal stability following orthognathic surgery	10/16
Franco et al. (2013)[19]	Long-term 3-dimensional stability of mandibular advancement surgery	Evaluate condylar remodelling and skeletal stability following orthognathic surgery	11/16
An et al. (2014)[20]	Effect of post-orthognathic surgery condylar axis changes on condylar morphology as determined by 3-dimensional surface reconstruction	Evaluate the effect of condylar axis changes on condylar remodelling	9/16
Xi et al. (2015a)[21]	3D analysis of condylar remodeling and skeletal relapse following bilateral sagittal split advancement osteotomies	Evaluate condylar remodelling and skeletal stability following orthognathic surgery	10/16
Xi et al. (2015b)[22]	The role of mandibular proximal segment rotations on skeletal relapse and condylar remodeling following bilateral sagittal split advancement osteotomies	Evaluate the effect of condylar axis changes on skeletal stability and condylar remodelling	12/16
Gomes et al. (2017)[23]	Counterclockwise maxillomandibular advancement surgery and disc repositioning: can condylar remodeling in the long-term follow-up be predicted	Evaluate condylar remodelling following orthognathic surgery with disc repositioning	11/16
Xi et al. (2017)[24]	Three-dimensional analysis of condylar remodeling and skeletal relapse following bimaxillary surgery: a 2-year follow-up study	Evaluate condylar remodelling and skeletal stability following orthognathic surgery	11/16
da Silva et al. (2018)[25]	Changes in condylar volume and joint spaces after orthognathic surgery	Evaluate condylar remodelling following orthognathic surgery	9/16

[a] MINORS, Methodological Index for Non-Randomized Studies.

Table 3. Overview of patients, type of surgery, and imaging.

Author (Year)	Number of patients Type of deformity	Type of surgery	CBCT type Field of view	Wax bite
Carvalho et al. (2010)[16]	27 Class II	18 BSSO 9 BSSO + genioplasty	NewTom 3G[a] 12-inch	Thin in centric relation
Goncalves et al. (2013)[17]	27 Class II	10 Bimax 17 Bimax + disc repositioning	i-Cat 22 × 16 cm	No (Manual guidance in centric relation)
de Paula et al. (2013)[18]	50 Class III	25 Le Fort 25 Bimax	NewTom 3G[b] 12-inch	Thin in centric relation
Franco et al. (2013)[19]	27 Class II	17 BSSO 10 BSSO + genioplasty	NewTom 3G 12-inch	Centric relation
An et al. (2014)[20]	30 Class III	15 BSSO 15 Bimax	DCT Pro 20 × 19 cm	No (Maximum intercuspation)
Xi et al. (2015a)[21]	56 Class II	56 BSSO	i-Cat 22 × 16 cm	No
Xi et al. (2015b)[22]	56 Class II	56 BSSO	i-Cat 22 × 16 cm	No
Gomes et al. (2017)[23]	41 Class II	41 Bimax + disc repositioning	i-Cat 23 × 17 cm	No
Xi et al. (2017)[24]	50 Class II	50 Bimax	i-Cat 22 × 16 cm	No (Manual guidance in centric relation)
da Silva et al. (2018)[25]	57 Class II	57 Bimax	i-Cat 23 × 17 cm	No

Bimax, bimaxillary surgery; BSSO, bilateral sagittal split osteotomy; CBCT, cone beam computed tomography.
[a] Two patients had at least one scan taken with a NewTom 9000 scan with a 9-inch field of view not including the chin.
[b] Ten patients had at least one scan taken with a NewTom 9000 scan with a 9-inch field of view not including the chin or condyles.

Segmentation protocols (Table 5)

Six studies used the open-source software ITK-SNAP (www.itksnap.org) for segmentation[16–19,23,25]. Only two of these studies provided details on how the segmentation was performed[17,25]. Goncalves et al. performed a manual segmentation, delineating the contours of the condyle in 300 axial cross-sectional slices[17]. da Silva et al. utilized a semi-automated segmentation using the region competition mode and corrected the result manually if required[25]. The remaining four studies using ITK-SNAP stated that a semi-automated

Table 4. Registration methods used in the included studies.

Author (Year)	Remodelling time frame	Registration method	Registration software	Rigid registration used for the condylar remodelling analysis protocol	Rigid registration used for other analysis
Carvalho et al. (2010)[16]	4–6 weeks postop. → 1 year postop.	Voxel-based on cranial base	Imagine	Yes, voxel-based	Yes
Goncalves et al. (2013)[17]	Immediate postop. → 1 year postop.	Voxel-based on cranial base	Imagine	Yes, voxel-based	No
de Paula et al. (2013)[18]	4–6 weeks postop. → 1 year postop.	Voxel-based on cranial base	MIRIT	Yes, voxel-based	Yes
Franco et al. (2013)[19]	1 year postop. → 3 years postop.	Voxel-based on cranial base	Imagine	Yes, voxel-based	Yes
An et al. (2014)[20]	1 month preop. → 1 year postop.	Surface-based condylar neck, mandibular notch and posterior border of mandibular ramus	Rapidform	Yes, surface-based	No
Xi et al. (2015a)[21]	1–4 weeks preop. → 1 year postop.	Voxel-based on cranial base, forehead and zygoma	Maxilim	No	Yes
Xi et al. (2015b)[22]	1–4 weeks preop. → 1 year postop.	Voxel-based on cranial base, forehead and zygoma	Maxilim	No	Yes
Gomes et al. (2017)[23]	1 week postop. → 16 months postop.	(1) Voxel-based on cranial base and (2) voxel-based on condylar region	3D Slicer, CMF registration	Yes, voxel-based	Yes
Xi et al. (2017)[24]	1–4 weeks preop. → 2 years postop.	(1) Voxel-based on cranial base, forehead, and zygoma, and (2) surface-based on posterior ramus border	Maxilim	Yes, surface-based	Yes
da Silva et al. (2018)[25]	Preop. → 18 months postop.	–	–	No	No

Preop., preoperative; postop., postoperative.

segmentation was performed, without further details.

An et al. applied Vworks 4.0 software (Cybermed Co., Seoul, South Korea) for condylar segmentation but did not provide further details on their segmentation workflow[20]. Xi et al.[21] presented a segmentation protocol validated in a previous study[9]. They used an 'enhanced condyle' approach using Maxilim software (Medicim NV, Mechelen, Belgium) for initial rendering, ImageJ software (National Institutes of Health, Bethesda, MD, USA) for thresholding, and EditMask software (Medicim NV, Mechelen, Belgium) for manual correction of the segmented object. Next, the enhanced condyle was superimposed on the original condyle in Maxilim and a semi-automated surface integrity check was performed using a programmed macro in Autodesk 3 ds Max software (Autodesk Inc., San Rafael, CA, USA). A last manual surface integrity check was performed using DeskArtes View Expert 8.1 software (DeskArtes Oy, Espoo, Finland). Xi et al. updated their protocol to a region-growing based semi-automated segmentation protocol for the remaining two studies[22,24]. The protocol remained an 'enhanced condyle' approach, although segmentation was now performed using a 3D region-growing algorithm designed and used in MATLAB software (MathWorks Inc., Natick, MA, USA)[27].

Analysis protocols (Table 6)

As for the effective analysis of the respective condylar remodelling, three techniques could be identified: condylar volume calculation, correspondent point calculation, and closest point calculation.

Five studies utilized volume calculation to evaluate condylar remodelling[21–25]. To obtain a delineated volume, the condylar surface is cut using a reproducible plane of choice and the volume of the resulting 3D object is calculated. Three studies chose a cut-off plane through the most inferior point of the sigmoid notch parallel to the Frankfort horizontal plane[21,22,24]. One study opted for an artificially created horizontal plane[25]. Gomes et al. did not specify how the volume of the condyle was delineated[23].

Correspondent point calculation was performed in two studies[18,23]. These studies used the SPHARM-PDM toolkit[28] to identify correspondent points in two condylar surfaces derived from segmentation of the follow-up CBCT scans and to calculate the distance and vector of displacement. This differs from closest point

Table 5. Segmentation methods used in the included studies.

Author (Year)	Voxel size (mm^3)	Software	Method
Carvalho et al. (2010)[16]	0.5	ITK-SNAP	No further details
Goncalves et al. (2013)[17]	0.5[a]	ITK-SNAP	Complete manual outlining
de Paula et al. (2013)[18]	0.5	ITK-SNAP	Semi-automated, no further details
Franco et al. (2013)[19]	0.5	ITK-SNAP	No further details
An et al. (2014)[20]	NA	Vworks 4.0	No further details
Xi et al. (2015a)[21]	0.4	Maxilim, ImageJ, EditMask	Creation of an enhanced condyle using thresholding (ImageJ) and manual correction (EditMask); the enhanced condyle is loaded into the initial rendering in Maxilim
Xi et al. (2015b)[22]	0.4	Maxilim, MATLAB	Creation of an enhanced condyle using thresholding and a region-growing segmentation initiated every 5 slices; interpolation connects the slices that were not given a seed point; the volume is checked and loaded into the initial rendering in Maxilim
Gomes et al. (2017)[23]	0.3–0.5[a]	ITK-SNAP	Semi-automated, no further details
Xi et al. (2017)[24]	0.4	Maxilim, MATLAB	Creation of an enhanced condyle using thresholding and a region-growing segmentation initiated every 5 slices; interpolation connects the slices that were not given a seed point; the volume is checked and loaded into the initial rendering in Maxilim
da Silva et al. (2018)[25]	0.4	ITK-SNAP	Semi-automated, region competition algorithm with manual correction

[a] Resampled voxel size of the CBCT image before segmentation.

calculations, which just calculate the distance between a point and the closest points of the surface rather than the correspondent point. Four studies opted for closest point analysis[16,17,19,20]. Two of these used CMF software (Maurice Müller Institute, Bern, Switzerland)[16,19]; An et al. used Rapidform XOS3 (INUS Technology Inc., Seoul, South Korea)[20] and Goncalves et al. utilized the VAM software 2012 (Canfield Scientific, Fairfield, NJ, USA; http://www.canfieldsci.com)[17].

Validation protocols (Table 7)

All studies validated their methods. Some studies did not state clearly if all steps (segmentation–registration–analysis) or only a subset (analysis) of their protocol were validated. Six studies performed a validation and reported the validation protocol in their paper[16–20,25]. The remaining four studies validated their protocol in a previous study and referred to that validated technique[21–24]. Most studies used inter- and intra-observer intra-class correlation techniques to validate their methods, with high intra-class correlation coefficients (ICCs), indicating a valid method.

Discussion

The purpose of this study was to identify and assess methods for the evaluation of condylar remodelling following orthognathic surgery using 3D models derived from CBCT data. Although the studies were heterogeneous in their research aims, all 10 evaluated condylar remodelling by means of 3D condylar models. This review identified three cornerstones in 3D condylar remodelling analysis – registration, segmentation, and analysis of remodelling – as outlined below.

Registration

Several rigid registration techniques are used to match and superimpose longitudinal CBCT scans. From a mathematical point of view, voxel-based registration is the most accurate and robust rigid registration technique[8,26,29,30]. Surface-based registration is inherently more prone to error in the registration process since it relies on the accuracy of the 3D surface construction. Landmark-based registration is even more prone to error[31].

Rigid registration starts with the selection of a region of interest for registration (ROIR). This ROIR is used by the registration software to match either the surface of interest in the case of surface-based registration or the VOI in the case of volume-based registration of the CBCT scans that need to be superimposed. The ROIR of the follow-up scan is then reoriented to the ROIR of the baseline scan, which leads to a reorientation of the whole image dataset based on this transformation[32].

Proper ROIR selection is a crucial step in an analysis protocol. The ROIR has to be chosen in accordance with the objective of the analysis. For the evaluation of condylar remodelling, the ROIR is preferably a structure that remains stable in position, showing no extensive postoperative remodelling[32]. Four studies chose the cranial base as the ROIR for condylar evaluation[16–19]. The problem with this approach is that no clear distinction can be made between displacement of the condyle and condylar remodelling. This displacement can be induced by the surgery itself or by not using a reproducible occlusion during scan acquisition, since the position of the condyle in its fossa is determined by occlusion. These studies did acquire each CBCT in centric relation to allow imaging with the mandible in a reproducible position in the glenoid fossa. A wax bite aids in this endeavour, but even then, guiding and keeping the mandible in centric relation to acquire the CBCT remains prone to error[33].

Ideally, a mandibular structure of the proximal segment is selected as the ROIR. This eliminates the need for a reproducible position of the mandible during image acquisition and the overlap of surgical displacement information. The posterior border of the mandibular ramus, the sigmoid notch, and the coronoid process seem ideal anatomical structures for the ROIR. Selecting the condyle as the ROIR was the method chosen by Gomes et al.[23] and was validated in a study by Schilling et al.[8]. However, if elaborate remodelling or resorption occurs in a small region such as the condyle, the question becomes whether voxel-based registration is still reliable in matching the identical anatomical voxels. To avoid this, the authors suggest keeping the region of interest for registration and the region of interest for analysis, i.e. the condyle, separated. Selecting areas such as the posterior border of the ramus, sigmoid notch, and

Table 6. Analysis methods used in the included studies.

Author (Year)	Volume analysis	Regional analysis	Analysis software	Method overview
Carvalho et al. (2010)[16]	No	Closest point calculation	CMF software, isoline tool	CMF tool calculated point-to-point comparisons between condylar surfaces of longitudinal models. This was displayed through the isoline tool which produced a colour-coded surface, corresponding with the amount of surface displacement.
Goncalves et al. (2013)[17]	No	Closest point calculation	VAM software	VAM calculated point-to-point distances at anterior, posterior, lateral, medial, and superior pole of the condyle.
de Paula et al. (2013)[18]	No	Correspondent point calculation	SPHARM-PDM toolbox	SPHARM-PDM identified anatomical correspondent points of the longitudinal condylar surfaces and calculated the distance and vector of displacement.
Franco et al. (2013)[19]	No	Closest point calculation	CMF software, isoline tool	CMF tool calculated point-to-point comparisons between posterior, anterior, lateral, medial, and superior condylar pole surfaces. This was displayed through the isoline tool which produced a colour-coded surface, corresponding with the amount of surface displacement.
An et al. (2014)[20]	No	Closest point calculation	Rapidform	Rapidform calculated the closest point-to-point distances of anterolateral, anteromedial, anteromiddle, posterolateral, posteromedial, and posteromiddle longitudinal condylar surfaces.
Xi et al. (2015a)[21]	Yes	No	Maxilim	Volumes of the enhanced condyle were calculated above the C-plane. This plane was identified in each scan as the plane parallel to the Frankfort plane through the most inferior point of the sigmoid notch.
Xi et al. (2015b)[22]	Yes	No	Maxilim	Volumes of the enhanced condyle were calculated above the C-plane. This plane was identified in each scan as the plane parallel to the Frankfort plane through the most inferior point of the sigmoid notch.
Gomes et al. (2017)[23]	Yes	Correspondent point calculation	(1) ITK-SNAP for volume and (2) 3D Slicer, SPHARM-PDM for correspondent point calculation	Condylar volume was calculated without details of cut-off plane. SPHARM-PDM identified anatomical correspondent points of the longitudinal condylar surfaces at the superior, anterior, posterior, medial, and lateral pole and calculated the distance and vector of displacement.
Xi et al. (2017)[24]	Yes	No	Maxilim	Volumes of the enhanced condyle were calculated above the C-plane. After surface-based registration of the proximal mandibular segment, the caudal border of the postoperative condyle could be defined by the preoperative C-plane.
da Silva et al. (2018)[25]	Yes	No	ITK-SNAP	Each mandible was reoriented to align the long axis of the mandible vertically. A cut-off plane was determined perpendicular to the coronal plane through the most inferior point of the sigmoid notch. The condylar volume was calculated above this plane.

coronoid process as the ROIR complies with this principle. Lastly, the baseline CBCT for condylar evaluation should be the CBCT taken immediately postoperative. The presence of the osteotomy creates a similar situation for segmentation and registration.

Segmentation

Before any accurate 3D morphological analysis can start, 3D models of the anatomical structures of interest have to be reconstructed from the CBCT DICOM data. Multiple software packages are available, which in turn use multiple tools for segmentation. The ground principle remains that the voxels of the desired anatomical structure need to be 3D-rendered towards a 3D surface or 3D volume model[13].

Nowadays, segmentation techniques have evolved to semi-automated methods in order to eliminate operator errors and facilitate a less time-consuming workflow. Thresholding and region-growing are two region-based methods that are mostly used[34,35]. Thresholding defines a range of grey values. If voxels fall into this range, they are included in the segmented object. Region-growing requires seed points to be identified in the desired structure. These are set as a signal intensity benchmark and adjacent voxels with the same properties will be included in the segmented object. Both thresholding and region-growing can be combined into one technique, 'dynamic region-growing'[36].

The mandibular condyles remain a challenge for segmentation out of CBCT data due to several factors: (1) low bone density, (2) connected soft tissues such as the articular disc, (3) the close relationship with the glenoid fossa, and (4) the intrinsic low contrast resolution of the CBCT data[9,37,38]. Segmentation results from semi-automated segmentation protocols therefore include connections of the condyle with the glenoid fossa or incomplete surfaces of the condyle. These have to be corrected manually, which might introduce operator error (analysis bias). Furthermore, due to the factors listed above, the condyles are likely prone to imaging

Table 7. Validation methods used in the included studies.

Author (Year)	Validation method	Validation instrument	Validation result
Carvalho et al. (2010)[16]	10 patients, 2-week interval, distance measurements	ICC intra-observer	High: ICC = 0.92
Goncalves et al. (2013)[17]	10 patients, 1-month interval, complete protocol	ICC intra-observer	High: ICC ranging from 0.78 to 0.99 for different condylar regions
de Paula et al. (2013)[18]	10 patients, 10-day interval, measurements	ICC intra-observer	High: ICC > 0.90%
Franco et al. (2013)[19]	10 patients, 15-day interval, measurements	ICC intra-observer	High: ICC > 0.99%
An et al. (2014)[20]	No details available	Cohen kappa index	High: 0.805
Xi et al. (2015a)[21],[a]	10 patients, 10-week interval (intra), 2 observers (inter), complete protocol	Mean intra- and inter-observer differences in volumes and surface distances	High: mean intra-observer difference in volume was 8.62 mm^3 and mean inter-observer difference in volume was 6.13 mm^3
Xi et al. (2015b)[22],[a]	10 patients, 2 observers, comparison with gold standard, condylar volume segmentation and calculation	(1) Inter-observer: 2-way mixed ICC and dice coefficient (2) Comparison with gold standard: dice coefficient	High: ICC of 0.97 and Dice coefficients of >0.94
Gomes et al. (2017)[23],[a]	(1) Registration: 12 patients, 2 observers (2) Analysis: specific study of defect simulation and detection	(1) Inter-observer ICC for regional registration (2) Defect simulation and detection study for SPHARM-PDM	High: ICC of >0.75 for regional registration and reliable functioning of SPHARM-PDM by specific defect simulation and detection study
Xi et al. (2017)[24],[a]	10 patients, 2 observers, comparison with gold standard, condylar volume segmentation and calculation	(1) Inter-observer: 2-way mixed ICC and dice coefficient (2) Comparison with gold standard: dice coefficient	High: ICC of 0.97 and Dice coefficients of >0.94
da Silva et al. (2018)[25]	11 patients, 1-month interval, complete protocol	ICC intra-observer	High: ICC 0.94

ICC, intra-class correlation.

[a] These studies used methods validated in other studies. The reported validation is the one of the validation study.

artefacts. If the patient's head is not positioned in a reproducible position during image acquisition, the mere altered position of the patient's head can cause a difference in image quality of already fragile condyles in the CBCT images[39]. This can then result in an inaccurate segmentation and analysis. Finding a reproducible head position with fixation aids could prevent this.

Most included studies did not elaborate on the method of segmentation or its validation and only disclosed the name of the segmentation software. The studies of Xi et al.[21,22,24], da Silva et al.[25] and Carvalho et al.[16] did report on specifics of how the segmentation was performed. As the segmentation process will create the surface and volume to be studied, a clearly stated protocol is essential. If the segmentation is inaccurate, an error is already incorporated into the result even before the effective analysis starts[40]. Further automation of the segmentation process derived from machine learning could lower the risk of operator error and may improve segmentation and analysis results[34].

Analysis of remodelling

With regard to the remodelling analysis, two approaches can be used: volumetric measurements of the 3D condylar model and inter-surface distance calculations.

For volumetric measurements, it is important to start from a reliable volume without artefacts and to identify a reproducible VOI for analysis. The key to obtaining a correct volume lies in a reliable segmentation protocol, as mentioned previously. A reproducible VOI can be obtained through different techniques. Four of the five studies specified a plane through the lowest point of the sigmoid notch parallel to a defined horizontal plane[21,22,24,25]. In order to decrease the operator dependent-error, this plane is produced only once per condyle on the first CBCT and then propagated to the follow-up CBCT. This technique was only used in one study[24].

The second approach to condylar remodelling analysis is an inter-surface distance calculation. The advantage of this approach is the identification of regions and types of remodelling. Theoretically, the condylar volume can remain unchanged if vertical height loss is compensated by an increase in transverse dimension. Inter-surface calculations can identify and categorize remodelling in specific regions. Two techniques for inter-surface calculation were used in the included studies: closest point and correspondent point calculations. Closest point calculations measure the distance between a point on a given surface and the closest point on the surface to which it is compared[41]. This closest point does not, however, automatically correspond to the same anatomical location, especially in the case of large deviations between the surfaces[28]. Correspondent point calculations use shape analysis to map the distance between correspondent anatomical points and should provide a more accurate result[23,28]. The SPHARM-PDM toolkit, now incorporated into 3D Slicer software (www.slicer.org), was the only software applying shape analysis[28].

To achieve a complete and accurate analysis of remodelling, volumetric and inter-surface distance calculations should be combined. The inter-surface distance calculations should be correspondent point-based and the VOI should be selected to mirror the anatomical locations of interest for remodelling such as the superior, anterior, posterior, lateral, and medial pole. These VOIs should be identical in all follow-up scans and could be transferred from the baseline image using registration techniques.

Recommendations

The studies reviewed provided a heterogeneous approach to the analysis of condylar remodelling using different techniques and software packages. All techniques were validated using different statistical analyses and the extent of the validation varied.

Based on these studies, the authors suggest the following criteria to achieve a high level of accuracy with a low chance of operator-dependent error (analysis bias) in a condylar remodelling analysis protocol (Fig. 2):

(1) Regional voxel-based registration of postoperative CBCT scans using an anatomical region not prone to postoperative change as the VOI. The mandibular ramus of the proximal part of the osteotomized mandible is an ideal candidate for the VOI.
(2) Application of a (semi-)automated segmentation protocol. At this time, dynamic 3D region-growing techniques combining thresholding and region-growing algorithms are advocated.
(3) The performance of a combination of volumetric condylar analysis and regional distance calculations. Shape analysis and correspondent point comparison provide a more accurate approach than closest point calculation. VOIs can be propagated in follow-up scans using regional registration techniques.
(4) All steps need to be validated using at least an inter-observer and intra-observer validation statistical analysis.

These criteria are proposed as a foundation for future research in condylar remodelling following orthognathic surgery. Homogenizing the condylar remodelling analysis protocols of different studies may provide an opportunity to gather large datasets for meta-analysis. These data could be linked to clinical symptoms such as TMJ pain or the occurrence of skeletal relapse to provide new insights into the effects of condylar remodelling and its progression to degenerative joint disease or condylar resorption. Regarding the implementation of these proposed criteria in clinical research protocols, several hurdles need to be overcome. First, digital planning and the follow-up of orthognathic patients need to be further encouraged. Preoperative CBCT as well as standardized follow-up scans at 1 and 2 years postoperative would seem appropriate for this goal. Next, registration, segmentation, and analysis would ideally be performed in one software suite that is easy to use. This is the biggest issue we currently face. Registration, segmentation, and analysis methods are dispersed over many software suites, of which most have been developed for engineers and computer scientists rather than clinicians. Acquiring and learning to use all of these programs is the reason why many clinicians may hold back from digital follow-up. Since we are now witnessing the emergence of many virtual planning software suites for orthognathic surgery, it would be interesting to see the incorporation of follow-up possibilities in these software suites. A condylar remodelling analysis protocol using the criteria suggested above could easily be incorporated as a follow-up module. By providing follow-up modules in already available virtual planning software suites, the number of studies performed could be increased and the data pool on this topic enlarged. Big data analysis could then eventually lead to reliable tools to predict the possible adverse effects of orthognathic surgery on the TMJ.

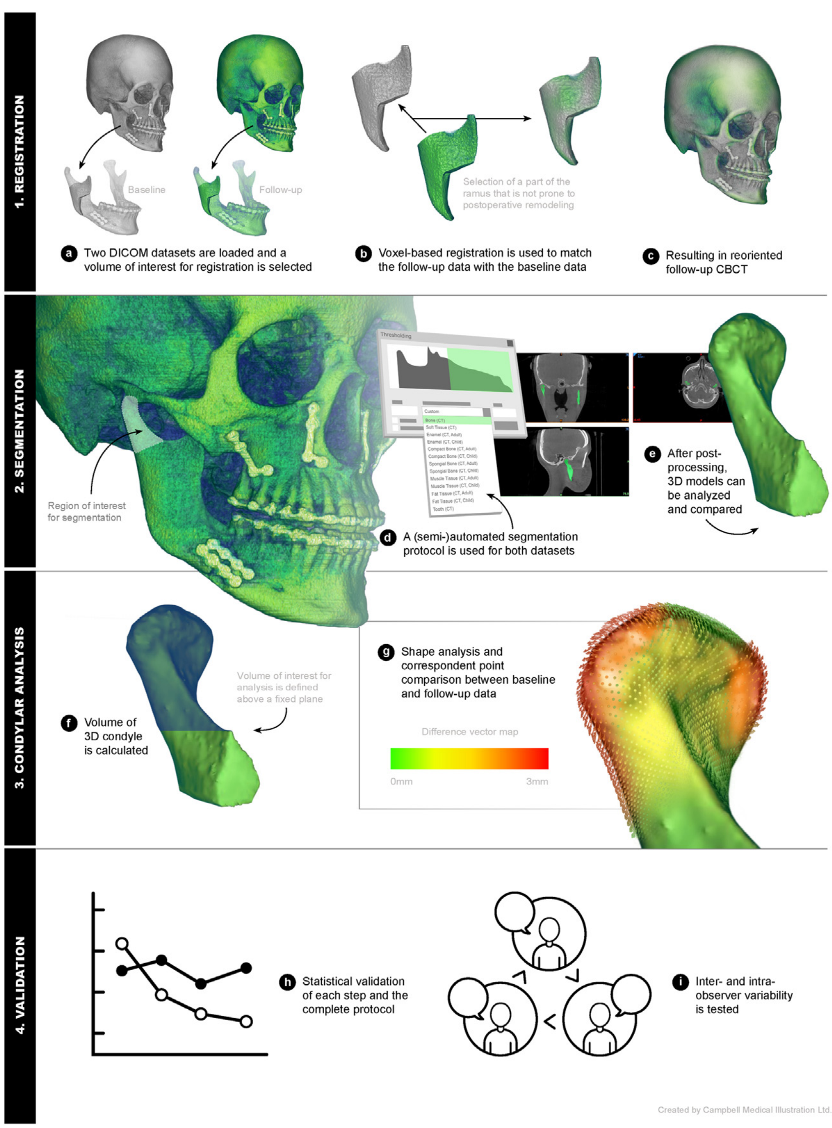

Fig. 2. Infographic illustrating the suggested criteria and steps for an accurate condylar remodelling analysis protocol.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.ijom.2019.05.009.

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