

**FEATURES
SECTION**

Current Products and Practice

How to create and manage a regional orthognathic database

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This is a report on the use of a regional database of patients undergoing orthognathic treatment in the South West of England. The benefits and difficulties of using a regional database are discussed.

Key words: Orthognathic, database

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Background

The use or benefit of databases within orthodontics has had little attention. However, comprehensive database systems have been recommended in recent studies, as a means of enabling identification and tracking of patients¹ and reducing bias from alternative methods of data collection.² Some well-established archives have been used to demonstrate orthodontic treatment effect and relapse, e.g. North Carolina Orthognathic series³ and Washington, Seattle, retention follow-up series.⁴

With growing emphasis on monitoring clinical outcomes of patients undergoing treatment,^{5,6} methods of following individuals through the treatment pathway may help identify subjects for subsequent audit or research. This is a key component of clinical governance and improving patient management, and is likely to be of relevance to clinicians worldwide.

In the arena of National Health Service (NHS) orthodontic practice, clinicians will increasingly need to be able to demonstrate outcome assessment particularly when undertaking complex combined treatment, which has relative high costs compared with standard orthodontic treatment. The need to establish a record of the numbers of patients who progress to treatment after initial consultation on joint orthognathic clinics with surgical and orthodontic consultant colleagues is essential. This would help to demonstrate the demand and the

relative costs of running such a service. Through annual appraisal, consultants are encouraged to give details of current workloads in relation to other colleagues both nationally and regionally, leading to an increasing need to be able to identify patients undergoing orthognathic treatment.

Development of a database

Since 1997 the orthodontic departments of the South West region of England have collaborated to maintain a co-ordinated regional database of patients undergoing orthognathic treatment. The information is stored using Microsoft® Access™ (Figure 1).

The aim of the database was to collect baseline information of patients who undergo joint orthognathic treatment in the South-West region. It was based on an existing departmental orthognathic database in the orthodontic department at Taunton and Somerset Hospital.

Details of the database

The refined database included the following generic details and free text boxes:

- patient hospital number;
- date of birth;

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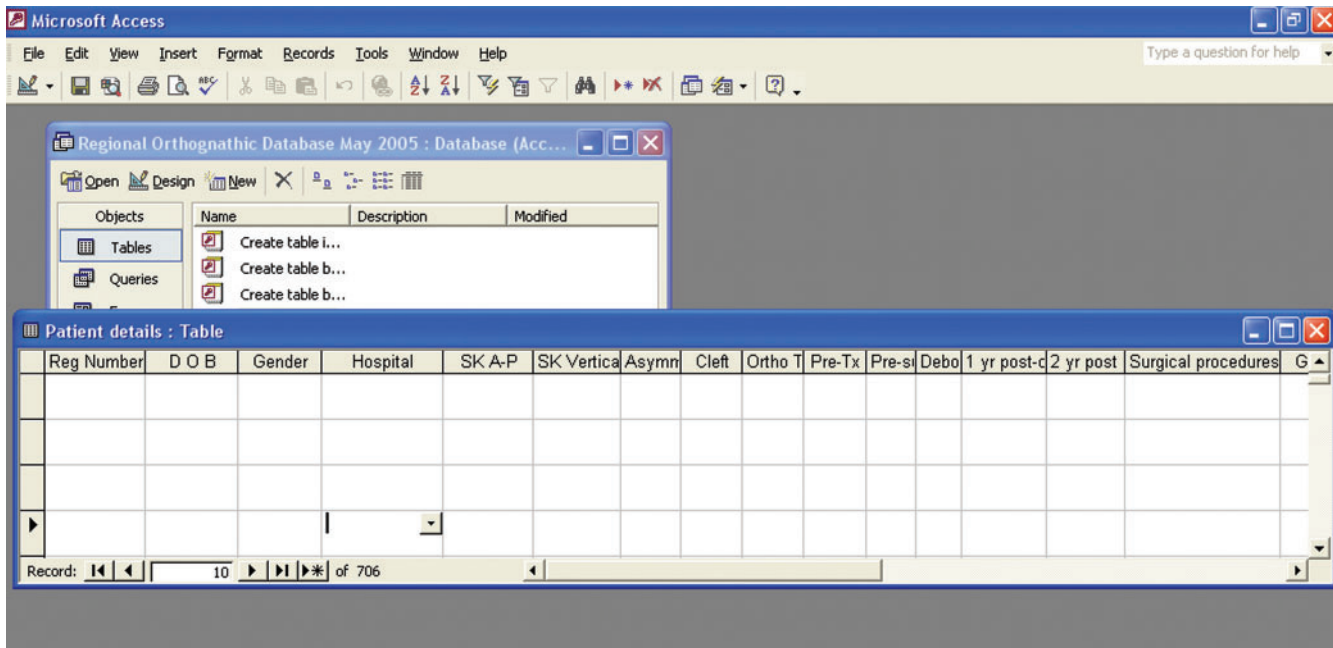


Figure 1 View of the database

- gender;
- presence of orofacial cleft;
- malocclusion;
- skeletal pattern;
- anterior-posterior;
- vertical;
- type of surgery;
- date of surgery;
- comments.

After the initial data collection had started, a decision was made to expand the remit of the database to include the collection of simple outcome measures such as overjet values (mm) at the start of treatment, pre-surgery and one year post-surgery. Later, the overjet values at two years post-surgery were added, in line with national guidelines.⁷

Originally, paper copies of the data collection form were forwarded from individual units twice a year to the central base (Taunton and Somerset Hospital) where the database was held. However, with the improvements in electronic communication, the forms are now transmitted electronically throughout the year. A number of boxes include drop-down menus to aid data input and standardization. The current data collection form is shown in Figure 2. Electronic forms are emailed directly to the database co-ordinator and bi-annually a spreadsheet of the existing information is sent to individual clinicians for further updating, attempting to ensure that all patients are included in the database. These forms are

stored on the co-ordinator's computer and backed up on the host's main server. Forms previously sent concerning that patient can be overwritten. Paper copies are also stored as a further back-up in case of any problems with the hard drive and back-up server. Should these ever occur, then at least the data would be available in paper format subsequently. Currently, the form does not interface directly with the database to allow direct entry of the information. This is manually entered by the co-ordinator. This is obviously a weakness as data entry errors can be introduced but this is subsequently checked by individual units when details of the inputted data are sent to units on the twice-yearly updating process mentioned above. Hopefully, improvements in computing skills and software may allow for automatic electronic data input in the near future. This is certainly something to investigate when deciding on the type of software to be used to design a database.

Current database

Since 1997, over 700 patients have been added to the database. This reflects the activity of the eight surgical units and 13 orthodontic units involved. Data collection is variable in its completeness for those entered onto the database. The majority of the absent data relates to patients operated on during late 2004 and 2005. This demonstrates the lag between data collection and actual clinical events. This difficulty has been discussed and no

Regional Database Forms : Osteotomies

Patient details

Hospital base - Hospital number -

Patient's date of birth -
(dd/mm/yy)

Patient's gender - Cleft patient -

Diagnosis

Skeletal pattern

Antero-posterior -

Vertical -

Transverse (asymmetry) -

Treatment

Orthodontic treatment -

Surgical procedure -

Genioplasty -

Operation date -
(dd/mm/yyyy)

Additional procedures -

Overjets

Pre-treatment - Pre-surgical -

Debond - 1 year post-op - 2 year post-op -

Comments -

Please return to: Mr Scott Deacon, Orthodontic Department, Taunton and Somerset Hospital,
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Or e-mail to scott.deacon@bristol.ac.uk
Form password = sac

Version 4 (1/12/04)

Figure 2 Electronic data collection form

workable solution has yet come to light. This reflects the different approach to the recording of joint treatment in different departments and the additional workload involved in completing the data forms. Currently, the data collection is the responsibility of the orthodontists in the region. Some discussion with oral and maxillofacial colleagues prior to the designing process may help identify who in an area will have responsibility for collecting the data and what data clinicians would like to have included in the database.

Uses of the database

The returned information allows the co-ordinator to report outcome and/or demographic details at one of the

biannual regional audit meetings (see Tables 1 and 2 for examples of the type of data presented at regional meetings and requested by colleagues within the region).

Data from Microsoft® Access™ can be easily imported into Microsoft® Excel™ for manipulation to produce descriptive statistics and graph generation (Figure 3).

The South-West region is divided into two areas for regional audit purposes. A 'North-South' divide exists. The descriptive outcome and demographic analysis are usually divided into two reports, which, include the activity of the region as a whole in order to allow for comparison. The reported data has included the following.

The screenshot shows a Microsoft Access window titled 'Microsoft Access - [Frenchay : Select Query]'. The main area displays a data table with the following columns: Reg Number, D O B, Gender, Hospital, SK A-P, SK Vertical, Asym, Cleft, Ortho, Pre-Tx, Pre-s, Debol, 1 yr post-d, 2 yr post, Surgical procedures, and G. The data rows contain patient information such as dates of birth, gender, hospital names, and various clinical measurements. A context menu is overlaid on the table, providing options for sorting, copying, pasting, and column management.

Figure 3 Data can be copied and pasted into Microsoft® Excel™ (hospital numbers anonymized)

Table 1 Example of the number of operations provided per year within some of the units.

Unit	Number of operations undertaken									
	Total no.	1998	1999	2000	2001	2002	2003	2004	2005	
Unit 1	28			5	5	4	6	8		
Unit 2	63			9	10	6	10	17	11	
Unit 3	43			8	7	5	9	12	2	
Unit 4	17	5	1	2	2	5	2			
Unit 5	49		6	7	1	2	13	17	3	
Total	200	5	7	31	25	22	40	54	16	

Table 2 Example of demographic data collected by operation type.

Operation	Total No.	1998	1999	2000	2001	2002	2003	2004	2005
Mandibular advancement +/- genioplasty	51		1	12	7	2	11	16	2
Mandibular Setback +/- genioplasty	7			3	2		1	1	
LeFort I +/- genioplasty	21	4	2	1	3	3	3	3	2
LeFort II +/- genioplasty	0								
LeFort III +/- genioplasty	0								
Bimax +/- genioplasty	107	1	4	15	11	16	22	30	8
Genioplasty only	0								
Total	186	5	7	31	23	21	37	50	12

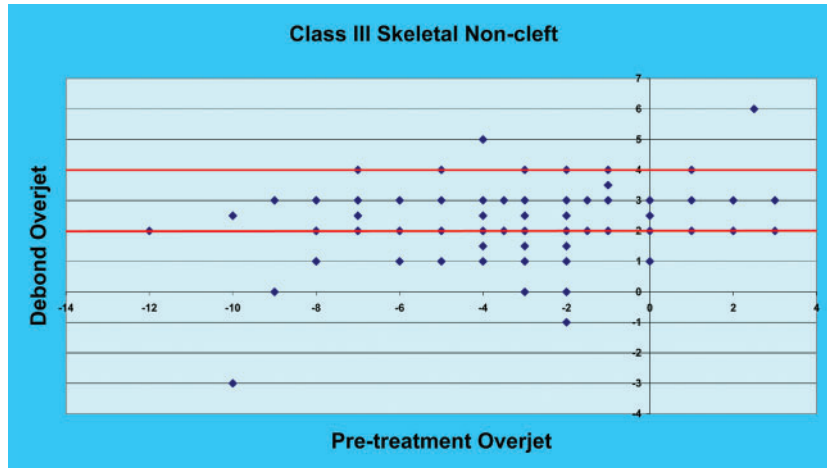


Figure 4 Comparison of pre-treatment overjet with that achieved by orthognathic treatment at the debond stage (red lines demonstrate 'ideal' overjet limits)

Outcome comparison

Outcome comparison data from the database includes overjet measurements during the course of treatment. This was chosen as a measure, because it is easy and quick to record and requires no specialized instruments. The overjet measurements highlight patterns of orthognathic treatment outcome as well as relapse in the anterior-posterior direction (Figures 4 and 5).

Demographic data

Presentations at regional audit meetings have included the following data:

- number of patients undergoing treatment for individual units and the region as a whole;

- gender distribution;
- operation patterns within the region (Tables 1 and 2);
- number of cleft patients receiving orthognathic treatment (Figure 6);
- skeletal discrepancy patterns (Figure 7).

Individual units are better able to assess their overall activity and relate this to the type of patients who are undergoing orthognathic treatment at that particular unit. Currently, data on cleft patients are recorded. It may be that, with the introduction of a national cleft database recording surgical outcome under development by the audit group of the Craniofacial Society of Great Britain and Ireland, input of the cleft data onto the local orthognathic database may cease. This should be relatively easy to address as all cleft orthognathic surgery is now carried out by the same surgeon for the region.

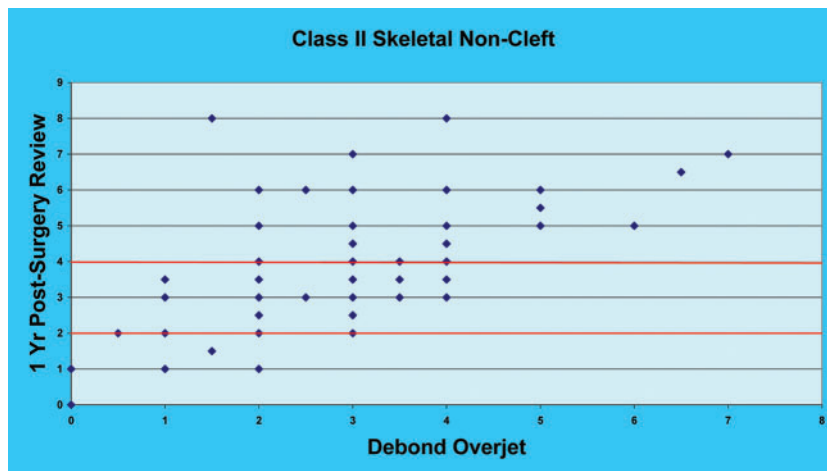


Figure 5 Stability and relapse of overjet correction in Class II orthognathic cases (red lines demonstrate 'ideal' overjet limits)

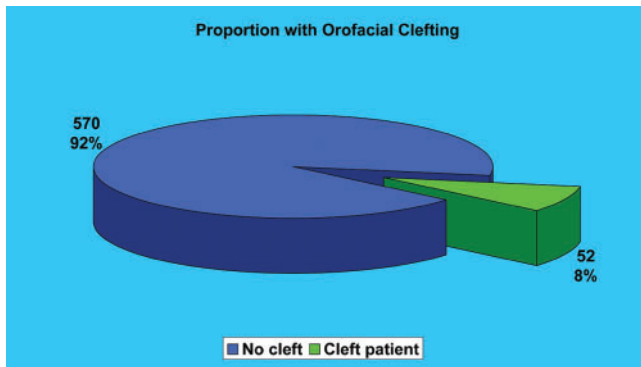


Figure 6 Proportion of treated cases with orofacial clefting

Information for individual units

The database can provide numeric data on activity levels for a particular treatment modality within units. These data can then be compared with activity in other regional units. It is also useful for the annual hospital consultant appraisal process.

The identification of subjects to assess the outcome or process of orthognathic treatment for local and regional audit and research is greatly simplified. Subsequent audits, involving cephalometric outcomes of treated cases has been found much easier to organize. The ethical and consent issues posed by this are discussed later.

Training for registrars

It can be difficult to gain managerial experience at the FTTA level of Specialist Registrar training within the limitations of a two-year fixed term contract. Managing and organizing a database of this type facilitates experience in liaising with regional consultant colleagues. It provides the trainee with an opportunity to gain experience in producing data requested by colleagues for specific deadlines as well as developing effective communication skills. These particular skills are essential in later consultant life. Gaining experience in running such a system may give the trainee an insight into how different departments structure their overall treatment of multidisciplinary patients.

Difficulties experienced in organizing and facilitating the database

Data protection

The Data Protection Act 1998⁸ and the Caldicott principles⁹ both highlight the need for managing databases to ensure ethical use of these systems. Whilst the database described here and the framework within which it operates must pertain specifically to

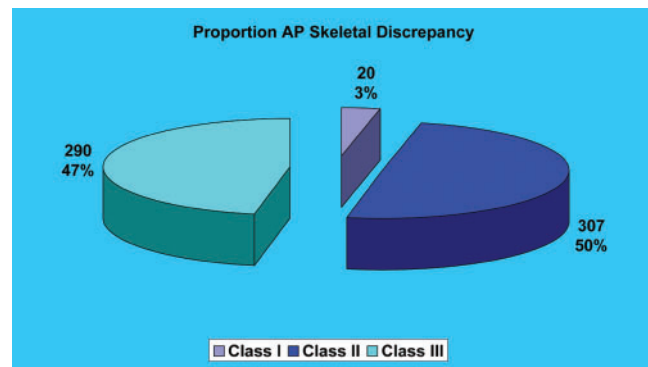


Figure 7 Distribution of treated cases as categorized by their antero-posterior skeletal relationship

England. Nevertheless, data protection is clearly an issue of universal concern, no matter where in the world it is set up.

Therefore, recording accurate information and robust updating processes should be in place to follow these principles. Spreadsheets of existing entered data are sent to individual units bi-annually for checking, to help with this process.

The data is stored on a password-protected computer, which is backed-up daily to an additional server in another part of the hospital. The password-protected version is only available to the database co-ordinator.

Another limitation of the data protection legislation is to reduce patient details sent via all forms of communication. Therefore, the electronic forms or database do not record the patient's name. Some units use a coding system to prevent the hospital number being included in the data entered into the database. The individual units are able to identify the patients at subsequent data entry points when requested by the co-ordinator. It may be with time that developing a password-protected format for data transfer helps to increase the security of this process of electronic transfer of patient data. Also the transfer of email services onto NHS.net services across the country may reduce the concern with electronic transfer as this provides an encrypted method of data transfer, ideal for sending patient information.¹⁰

Ethical issues

Ethical approval. This is a difficult area when considering setting up a regional database. COREC (Central Office for Research Ethics Committees) advice does not directly cover this issue and no written guidance is available to interpret. On the COREC website the only guidance relates to types of activities that require ethical approval.¹¹ Research does require ethical approval, as would the use of any data on the

database for subsequent research-based projects. COREC also suggests the audit projects and service level projects do not require ethical approval, but are unclear on the role of a database. This is a grey area and it would be suggested that, in the current climate, contact is made with your local LREC (Local Research Ethics Committee) for advice concerning this area. For example, information regarding the design, data collection, storage and consent issues will probably need to be supplied, as well as information on how these matters would be tackled in the setting up process.

Patient consent. This is also a grey area. Certainly, this issue was not perceived as a problem when establishing the current database in 1997. Currently, any use of a database for research would require patient information in a written format and a specific consent form addressing the use of data stored on the database for research. Whether consent is required for data to be stored on the database *per se*, is a more difficult argument. This can be difficult to implement and putting robust mechanisms in place to allow patients to remove their consent at later stages, is challenging. This has certainly been one of the author's experiences when dealing with this issue in relation to the centralized cleft database (CRANE). Advice from COREC has suggested that if you are developing a database, that patient consent should be sought as a matter of good practice.¹² In recent history, the authors have discussed the issue of patient consent and have not introduced this so far. If, however, with changing advice we decided to introduce consent, then the generic consent forms used for treatment would not fulfil this role and a specific consent form would be required to make this process as robust as possible. Details of the information stored, how it is stored and who has access to it would be required as part of this form.

Changes in practice and measures over time that alter data collection regimes

With new developments, such as the joint British Orthodontic Society (BOS) and British Association of Oral and Maxillofacial Surgeons (BAOMS) guidelines⁷ for data collection with orthognathic treatment, the database has needed to be flexible to allow modification for these changes to occur in practice.

As measures for orthognathic outcome develop, there should be some flexibility to include further data; this can be undertaken in MicrosoftTM Access[®]. This may include PAR Indices¹³ scoring of the occlusal outcome or altered sensation presence as outlined on the BOS/BAOMS minimum dataset form.⁷ Therefore, constant

updating and review of the database's format is crucial to ensure it remains relevant and useful. This must be weighed against the need to keep data collection simple, so as to encourage completed data entry.

Service levels

Another issue in the current climate is the quality of care and service levels. Table 1 shows that workloads per year do differ between units, and relates to the different number of orthodontists and maxillofacial colleagues at these units. Low volume operators may come under some pressure to stop providing an orthognathic service, either due to cost effectiveness in the currently cash-strapped NHS or to concerns over quality of outcome. This concern arises from indirect comparisons with other services, i.e. with cleft care.¹ Certainly, patients would be easily identified for any subsequent audit project to assess outcome, which could be used to address such issues as quality of outcome versus the number of procedures undertaken.

Some units shown in Table 1 have seen increases in the activity per year during the time data has been entered onto the database. This may demonstrate an increasing demand and may help to justify expansion of this type of service to cope with this demand. Clearly, careful consideration is needed in order to ensure service level data is used and distributed in an appropriately informed manner.

Summary

Establishing a database of all orthognathic treatment provided in a region may seem a daunting task, and it does require a number of hours in development and the collaboration of colleagues for it to be successful. Our experience has been that the work required in developing and maintaining such a database is outweighed by the benefits provided. Subsequent audit, research, monitoring and appraisal processes have all benefited from the use of the Regional Orthognathic Database.

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