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Storage of Fractional Flow Reserve Hemodynamic Waveforms Using Semantic Extension of the DICOM Standard

Nikolaos Kakouros [1]

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Abstract Visual assessment of coronary stenoses by coronary angiography remains widely used but correlates poorly with ischemia, particularly for moderate lesions. Fractional flow reserve (FFR) is a cardiac catheterization procedure that aims to provide objective measures of coronary lesion hemodynamic significance and involves the acquisition of phasic pressure and electrocardiographic waveforms. The dataset from these procedures currently remains in proprietary systems with restricted data access, inability for data exchange, and often inadequate archiving. Digital Imaging and Communications in Medicine (DICOM) includes a waveform information object definition. We describe the method of encapsulating FFR procedural information into a DICOM waveform file. We define private data elements to capture modality-specific data that is not represented by standard DICOM data elements. We propose the adoption of this semantic extension of the DICOM waveform information object for exchange and archiving of data from studies of pressure-derived indices of coronary stenoses.

Keywords Fractional flow reserve · DICOM · Waveform IOD · Private data elements

✉ Nikolaos Kakouros
nikolaos.kakouros@umassmed.edu

[1] Department of Cardiovascular Medicine, University of Massachusetts, 55 Lake Ave North, Worcester, MA 01655, USA

Introduction—Clinical Importance of Fractional Flow Reserve

Coronary atherosclerotic disease is now a leading cause of mortality and morbidity globally [1]. Invasive coronary angiography remains the standard technique for establishing coronary anatomy, yet visual assessment of coronary luminal stenoses correlates poorly with ischemia. Furthermore, noninvasive testing is often not available or may fail to identify the stenosis responsible for ischemia, particularly in the presence of multivessel disease [2]. Fractional flow reserve (FFR) is a physiological index derived by invasively measuring pressure in the coronary arteries during maximal hyperemia and correlates well with objective myocardial ischemia [3]. FFR thus allows the identification of lesions responsible for ischemia, independently of their angiographic appearance, and allows for appropriately targeted interventions to these stenoses leading to improved clinical outcomes (reviewed in ref. [4]).

Given the importance of FFR measurements on clinical decision making, their effective documentation, exchange, and safe archiving are of paramount importance. We discuss herein the practicalities of FFR measurements, the shortcomings of current exchange and archival methods, and propose a semantic extension for the exchange and storage of FFR datasets within the Digital Imaging and Communications in Medicine (DICOM) standard.

FFR Procedure and Data Collection

Coronary pressure-derived FFR requires the simultaneous recording of aortic pressure (Pa) along with the distal coronary artery pressure (Pd), beyond a stenosis, during induction of maximal hyperemia [5]. The minimal stable Pd/Pa ratio at maximal hyperemia is recorded as the FFR by the analysis software algorithm. More recently, resting indices including novel algorithms such as the Instantaneous wave-free ratio (iFR®, Volcano Corp., San Diego, CA) have been used to analyze the pressure data but additionally mandate the concurrent recording of an electrocardiographic (ECG) signal to determine appropriate diastolic intervals. FFR, iFR, and resting Pd/Pa measurements are subsequently collectively referred to as FFR for simplicity.

Current Data Management

The hemodynamic data obtained during FFR may be directed to the catheterization laboratory hemodynamic system or specialist hardware provided by the pressure sensor manufacturers. The former method of employing the catheterization laboratory hemodynamic system uses proprietary protocols for data storage, such that data can often only be reviewed by the specific acquisition system and exchange to other systems becomes impossible. By contrast, the use of specialist FFR analysis hardware is most commonly employed as new software and proprietary algorithms in the analysis of the signals can be more readily deployed. It is estimated that approximately 70 % of FFR hemodynamic data is managed by such systems (personal communication).

Many of the proprietary FFR systems already provide DICOM storage of the FFR results, but this is restricted simply to a static image of the algorithm-derived FFR result in a Secondary Capture Image Storage DICOM object (SOP Class UID 1.2.840.10008.5.1.4.1.1.7). Original phasic pressure waveform data may be manually exported from the hardware, but it is not archived within the DICOM object, and consequently, the hemodynamic measurements cannot be easily re-analyzed, are not integrated in the patient record, and are not safely stored [6].

Multiple technical issues in the recording may lead to erroneous FFR evaluation by the analysis algorithm. Such issues include significant arrhythmia, loss of Pd or Pa pressure signal during recording, dampened Pa waveform, or sensor drift [7]. In a recent study, using a core laboratory for the analysis of hyperemic and resting pressure-derived indices of the severity of stenoses, 19.3 % of recordings had to be excluded due to the identification of technical errors/uncertainties [7]. In view of the above, and the impact of these hemodynamic measurements in clinical decision making, their appropriate archiving is of high clinical importance.

FFR Within the DICOM Standard Context

DICOM was developed as an image exchange protocol and became the accepted standard for storing catheterization laboratory angiographic images but is also widely used for ultrasound, magnetic resonance, computed tomography, and other imaging modalities [8].

In addition, the DICOM working group on cardiac and vascular information (WG1) developed a waveform standard to meet the specific needs of hemodynamic and ECG recordings using the DICOM composite information object definition (IOD) model as the base for the waveform format [9]. Development was based on the European Committee for Standardization's prior work on an electrocardiography standard (CEN SCP-ECG) as well as the Health Level-7 v.2.3 waveform observation. The standard was ratified as an official extension in DICOM Supplement 30, but adoption remains poor [10].

With waveform data being another class of DICOM information objects, existing infrastructure for DICOM object management, used for catheterization laboratory angiographic imaging, can be leveraged to accommodate the FFR dataset with minimal additional implementation effort. FFR and non-hyperemic pressure-derived indices of coronary stenoses rely on the maintenance of referential relationships between ECG, waveform, and measurement data points that can be readily maintained within the DICOM framework.

The waveform information object definition for DICOM is harmonized at the semantic level with the HL7 waveform observation definition to allow easier interface between systems using HL7 and those using DICOM. It also utilizes controlled vocabulary attributes that render it easier to adapt to specialized clinical context such as the intravascular hemodynamic measurements of FFR evaluations.

Methods

FFR Waveform Information Object Definition

The basic structure of the proposed FFR Waveform file is based upon the DICOM standard described in detail elsewhere [11]. In brief, the file starts with a 128-byte File Preamble within which, for the purposes of the proposed FFR Waveform extension, all bytes shall be set to (00H). This is followed by a 4-byte DICOM prefix holding the uppercase character string "DICM" encoded using ISO 8859. The DICOM File Meta information is completed by File Meta Elements which are defined in Group Number (GN) 0002 in the DICOM Data Dictionary [12].

The subsequent FFR DICOM Data Set comprises of Data Elements of the Waveform IOD. Data elements are tagged by a Group Number and an Element Number (EN). Standard elements are granted even GNs, other than (0000,eeee), (0002,eeee), (0004,eeee), and (0006,eeee) reserved for DIMSE command and DICOM File Formats. The odd-numbered GNs other than (0001,eeee), (0003,eeee), (0005,eeee), (0007,eeee), and (FFFF,eeee) are available for Private

Data Elements used to extend the DICOM semantics [13]. The Data Element proposed for the FFR extension holds the explicit value representation (VR) of the element, Data Element Tag, Value Length, and Value for the Data Element using an Implicit VR structure. Nesting of datasets using Sequence of Items (SQ) Data Element is used recursively to create multilevel nested structures [11]. The special Data Elements of Item (FFFE,E000), is delimitated by an Item Delimitation Item (FFFE,E00D) with Value Length 00000000H and no Value Field. Similarly, a Sequence Delimitation Item (FFFE, E0DD) with Value Length 00000000H delimits the end of a sequence with undefined length. Within the above requirements, an FFR Waveform object extension can be effected by the definition of Private Data Elements to capture FFR therapy-related and physiological parameters that cannot be represented by Standard Data Elements.

FFR DICOM Waveform Base

The DICOM Data Dictionary assigns the SOP Class unique ID of (1.2.840.10008.5.1.4.1.1.9.2.1) to Hemodynamic Waveform Storage so this is set in the SOP Class UID tag (00008,0016), whereas the Modality Tag (0008,0060) is "HD". The DICOM Waveform Object, of which the proposed FFR object is an abstraction, is somewhat more complex that other DICOM objects and designed to generically hold waveform data ranging from hemodynamic phasic pressures to audio files. The Waveform IOD modules are shown in Table 1. Standard data elements are inherited from the waveform base class and include basic patient demographic information, study identifier, equipment identification, and procedural description.

The proposed FFR object inherits the attributes of the Waveform module Data Elements. It carries two channels of time-sampled phasic pressure data to represent the distal coronary (Pd) and concurrent aortic pressures (Pa) and a third channel for the ECG waveform. The channels carry synchronous data, are sampled at the same rate, have the same time extent, and are multiplexed into a single multiplex group sampled at a common frequency. The waveform module contains data elements to describe technical attributes including the number of channels, the common sampling frequency, and waveform bit allocation. Each channel also carries its own full technical definition and attributes for sensitivity, anatomical location, sensitivity correction factor, time skew, low and high filter settings, etc. [14].

Important attributes are highlighted in Table 2. The Channel Source Sequence (003A,0208) identifies the metric (e.g., voltage for ECG waveform or pressure in mmHg for phasic pressure waveforms), the anatomical position of the sensor or probe, and technique such as multilocation recording and pullback that may affect the parameters.

The currently defined context ID for the Channel Source Sequence (003A,0208) in each Channel Definition Sequence item for the ECG channel is based on DICOM-defined Context ID 3001 (ECG Leads) that can be adequately used to define the ECG channel source. The Hemodynamic Waveform Sources are defined in Context ID 3003. This defines multiple static and pullback-mode measurements from various intracardiac structure locations but has no provision for intracoronary anatomical locations.

Since the full source semantics cannot be carried in a single coded entry, the Channel Source Modifiers Sequence (003A, 0209) is used to carry additional qualifiers of the waveform source semantics. Technique terms are defined in Context ID 3241 and pertinently for FFR measurements include static (PA-50036) and pullback (PA-50033) methodologies.

Cardiac anatomical locations utilize terms from defined Context ID 3014 that carries coronary artery segments that can be used to code the original position of the distal pressure sensor. In the context of these measurements, the secondary position in case of pullback measurements can be assumed to be the guide catheter. The defined Context ID 3019 carries cardiovascular anatomic location modifiers that include coronary graft segments. Using the above, the anatomical and clinical relevance of the waveform data can be fully defined.

FFR DICOM Waveform Class

Although storage and exchange of the ECG and phasic pressure waveform data are of prime importance, the clinical context for their interpretation comes from ancillary data that also needs to be recorded in the FFR information object. This most pertinently includes the derived measures as recorded at the time of the procedure, such as the FFR, iFR, or Pd/Pa values. These derivatives may be associated with and exchanged alongside the waveforms using the Waveform Annotation Module as discussed below. Additional persistent Service-Object Pair Instances with unique identifiers (uIDs) are created alongside the waveform object to carry the clinical context information.

During recording, the acquisition unit can annotate the pressure waveforms with the time point identified by the FFR recording algorithm as demonstrating minimal and stable Pd/Pa, at which interval the FFR measurement was obtained. Annotations within the DICOM image IOD model are effective overlays operating at the display rather than semantic level so a separate Waveform Annotation Module that can be carried within the Waveform IODs was introduced as part of DICOM Supplement 30 on Waveform interchange [10].

These data are carried in a Waveform Annotation Module, consistent with the DICOM Supplement 23-introduced Structured Reports; the attributes of which are listed in Table 3 [15]. The Waveform Annotation Module can be used to hold the waveform-derived FFR data and even associate them with the

Table 1 DICOM Hemodynamic Waveform IOD modules

IE	Module	Usage
Patient	Patient	M
	Clinical trial subject	U
Study	General study	M
	Patient study	U
	Clinical trial study	U
Series	General series	M
	Clinical trial series	U
Frame of reference	Synchronization	C—used if waveform originality (003A, 0004) is ORIGINAL
Equipment	General equipment	M
Waveform	Waveform identification	M
	Waveform	M
	Acquisition context	M
	Waveform annotation	C—used is annotation is present
	SOP common	M

Modality value (0008,0060) is HD

Usage is mandatory (*M*), user optional (*U*), or conditional (*C*). *SOP* service object pair

waveform region used for derivation. The Unformatted Text Value Attribute (0070,0006) can utilize the concept names for the principal algorithms used in the result derivation. Nonetheless, instead of using plain text strings, we propose that the mutually exclusive Concept Name Code Sequence (0040, A043) is used instead to convey semantics. In the absence of a suitable Context Group, private codes for FFR, iFR, and Pd/Pa are proposed instead and defined using Basic Code Sequence Macro Attributes (Table 4).

The annotation should be applied to both phasic pressure and ECG channels in Referenced Waveform (0040,A0B0) by reference to channel 0. Similarly, the Referenced Sample Positions (0040,A132) direct the tag to the temporal range in the waveform from which the numeric measurement was derived. For range definition, Temporal Range Type (0040,A130) is set to SEGMENT. Finally, the result of the study is carried in Numeric Value (0040,A30A). It is noteworthy that since these derived measurements are ratios of pressures, they have no

Table 2 Waveform module major attribute elements

Tag	VR	Attribute	Attribute description
(5400,0100)	SQ	Waveform Sequence	Waveform sequence (1 to 4 inclusive)
(003A,0004)	CS	>Waveform Originality	Waveform originality (ORIGINAL/DERIVED)
(003A,0005)	US	>Number of Waveform Channels	Number of channels in multiplex group (1 to 8 inclusive)
(003A,0010)	UL	>Number of Waveform Samples	Number of samples per channel
(003A,001A)	DS	>Sampling Frequency	Sampling frequency in hertz
(003A,0200)	SQ	>Channel Definition Sequence	Channel definition sequence (one item per channel)
(003A,0208)	SQ	≫Channel Source Sequence	Channel source sequence
(003A,0209)	DS	≫Channel Source Modifier Sequence	Channel source modifiers to further qualify waveform origin
(003A,0210)	DS	≫Channel Sensitivity	Channel sensitivity—numeric unit quantity of sample (mmHg for pressure and V for ECG channels)
(003A,0211)	SQ	≫Channel Sensitivity Unit Sequence	Channel sensitivity units sequence
(003A,0212)	DS	≫Channel Sensitivity Correction Factor	Channel sensitivity correction factor
(003A,0213)	DS	≫Channel Baseline	Channel baseline (offset of encoded sample values from zero)
(003A,0214)	DS	≫Channel Time Skew	Channel time skew (offset of channel from waveform multiplex group start time in seconds)
(5400,1010)	OW	>Waveform Data	Waveform data—encoded data samples

VR value representation, *SQ* sequence of items, *US* unsigned short, *CS* code string, *OW* other word string, *UL* unsigned long, *DS* decimal string

Table 3 Waveform Annotation Module Attributes

Tag	Attribute	Attribute description
(0040,B020)	Waveform Annotation Sequence	Sequence of annotation items; one or more items shall be present
(0070,0006)	>Unformatted Text Value	Text Observation Value (annotation). Mutually exclusive with Concept Name Code Sequence (0040,A043)
(0040,A043)	>Concept Name Code Sequence	Code representing the fully specified name of the NUMERIC measurement or CODED concept. This sequence shall contain exactly one item. Mutually exclusive with Text Value (0070,0006)
(0040,A195)	≫Modifier Code Sequence	A sequence of items modifying or specializing the Concept Name. Any number of items may be present. Required if Concept Name Code Sequence (0040,A043) is sent and the value does not fully describe the semantics of the measurement or concept
(0040,A168)	>Concept Code Sequence	A sequence that conveys the categorical coded nominal value
(0040,A30A)	>Numeric Value	Numeric measurement value or values
(0040,08EA)	>Measurement Unit Code Sequence	Units of measurement. Coded entry sequence with one item only
(0040,A0B0)	>Referenced Waveform Channels	List of channels in waveform to which annotation applies
(0040,A130)	>Temporal Range Type	Required if Annotation does not apply to entire Referenced Waveform Channels. Type of annotated resion is POINT/MULTIPOINT/SEGMENT/MULTISEGMENT/BEGIN/END (see ref. [1] for details)
(0040,A132)	>Referenced Sample Positions	List of samples within a multiplex group specifying temporal points for annotation. Position of first sample is 1. Required if Temporal Range Type (0040,A130) is present and if Referenced Time Offsets (0040,A138) and Referenced Datetime (0040,A13A) are not present
(0040,A138)	>Referenced Time Offsets	Specifies temporal points for annotation by number of seconds after start of data. Required if Temporal Range Type (0040,A130) is present and if Referenced Sample Positions (0040,A132) and Referenced Datetime (0040,A13A) are not present
(0040,A13A)	>Referenced Datetime	Specifies temporal points for annotation by absolute time. Required if Temporal Range Type (0040,A130) is present and if Referenced Sample Positions (0040,A132) and Referenced Time Offsets (0040,A138) are not present
(0040,A180)	>Annotation Group Number	Number identifying associated annotations

Application in the FFR modality is discussed in main text. Concept Name Code Sequence (0040,A043) conveys semantics for the principal algorithm for FFR result derivation, using Basic Code Sequence Macro Attributes in Table 4

units of measurement, and a Code Value (0008,0100) of 1 in the Unified Codes for Units of Measurement (UCUM) standard adopted by DICOM. As, however, unity is forbidden as a Code Meaning in Measurement Unit Code Sequence (0040, 08EA), the Numeric Value must be specified as being a ratio by using ({ratio},UCUM,"ratio") [16].

Although the Annotation Module can be used as an auxiliary carrier of this data, we additionally recommend the use of the Waveform IOD semantic extension with Private Elements to provide further clinical context for the FFR measurements. Certain additional contextual information for the FFR data acquisition are specific to this modality and cannot be captured within DICOM data dictionary standard elements such as hyperemic status (e.g., adenosine infusion) [9]. Specific techniques such as a pullback of the coronary pressure transducer back to the guide catheter to obtain a pressure map along the coronary vessel length are also collected within each channel as described above.

Private Attributes are defined to encode this important additional data. The handling of Private Data Elements includes

Table 4 Code Sequence Macro Attributes for private codes

Tag	Attribute	Attribute description
(0008,0100)	Code Value	Private code value for FFR procedure; enumerated FFR/IFR/PDPA
(0008,0102)	Coding Scheme Designator	Private coding scheme; enumerated "99FFR"
(0008,0103)	Code Scheme Version	Private coding scheme version; enumerated 1
(0008,0104)	Code Meaning	Private code meaning; enumerated "Fractional Flow Reserve"/"Instantaneous wave-free ratio"/"Resting PdPa"

Used to convey FFR procedure semantics in Concept Name Code Sequence (0040,A043) provisions for handling the possibility of different implementers defining private data elements with the same group number. In brief, DICOM reserved a Private Creator Data Element group with Attributes (FFFF,0010-00FF) for reserving blocks of Private Data Elements at (gggg,1000-FFFF). Within these DICOM provisions, we propose a number of Private Data Elements with Group Number 0045 for FFR-specific parameters and information (Table 5). The Private Attribute definitions within the Information Object Definition and Data Element Keywords are also indicated.

Integration with Angiographic Imaging

Recently, a further application of intracoronary hemodynamics has been described, wherein the pressure-derived parameters are recorded along the length of a coronary artery during a pullback of the distal transducer. This can provide a physiological gradient map of functional coronary lesion severity. Analysis of this dataset can then be used to predict the effects of intervention to different parts of the coronary vessel [17]. One of the specific technical considerations in such an implementation is the requirement for exact time synchronization between the different modalities. Currently, for example, the hemodynamic system and image acquisition system have internal clocks that are not synchronized. Although the DICOM Waveform standard has provision for multimodality synchronization [10], integration platforms to bring together all this information under a common procedural context are becoming available from a number of intracoronary pressure sensor manufacturers. This is particularly important as the integration systems establish a temporal frame of reference and provide direct synchronization between the different datasets using time offsets.

In view of this, provision is made for imaging (angiographic) objects to be included along with the other FFR Waveform objects to provide a complete repository of the FFR study dataset within the DICOM infrastructure. These novel hybrid data can be stored alongside the Waveform objects using the existing DICOM Image IOD. Adopting the use of a common DICOM structure as described herein will facilitate further interoperability between these systems.

DICOM Waveform Information Object Adoption Outlook

The currently employed DICOM storage method employed by FFR integration systems utilizes the DICOM Secondary Capture Image IOD object carrying derived data and is inadequate. It does not allow for appropriate data archiving, quality control inspection, and re-analysis. It is akin to performing a complete imaging scan but only retaining in DICOM storage the single frame with the derived information while effectively discarding the original image dataset. In addition to the quality control issues discussed previously, discarding the original data and retaining only derived information may also carry potential medicolegal implications [18]. By contrast, the functionality discussed in this manuscript is a readily implemented semantic extension of the DICOM waveform object for FFR data exchange. It provides a means of FFR data encapsulation that allows for easy exchange and archiving, quality control, and retention of the original dataset for future re-analysis and research purposes. Furthermore, in view of HL7/DICOM interoperability, the structured data collection of derived data values (FFR, iFR, and Pd/Pa) can be directly interfaced to the cardiac catheterization laboratory reporting system and retrained in the patient's electronic medical record [19].

Conclusion

Pressure-derived coronary evaluation is the most validated invasive technique for the functional assessment of coronary stenoses and strongly guides clinical management decisions with marked effects on patient outcomes. The currently available DICOM storage methods provide very limited, static, and derived information and exclude the original dataset from DICOM archiving. By extending the DICOM waveform definition and private data elements, we propose a means of

Table 5 Waveform Private Attributes

Tag	VR	Keyword	Attribute description
(0045,0010)	LO		Private Creator; enumerated "FFR PRIVATE"
(0045,1000)	CS	Hyperemia	Hyperemic state; enumerated REST/HYPEREMIA
(0045,1001)	US	Venous input	Venous pressure (mmHg)
(0045,1002)	CS	Pullback	Pullback method employed; enumerated STATIC/MANUAL/AUTOMATIC
(0045,1003)	CS	Algorithm	Algorithm used; enumerated values FFR/IFR/PDPA
(0045,1004)	FL	Result	Numeric measurement value (result of algorithm)

Defined in Private Group (0045). The proposed enumerated values for (0045,1003) represent the principal algorithms used in the derivation of the study result adopting the DICOM Waveform information object for the storage and exchange of datasets derived from pressure-derived coronary evaluation procedures. We strongly recommend to the equipment manufacturers the adoption of these DICOM waveform objects for this clinically invaluable information for archiving, exchange, quality control, medicolegal, and research purposes.

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