CAD/CAE/CAM and RE/RP/RT (3C/3R)於顱顏牙科力學之應用研究及醫療器材法規介紹

The Application of CAD/CAE/CAM and RE/RP/RT (3C/3R) in Dental/Craniofacial Biomechanics and Introduction of Medical Device Regulations for Implant

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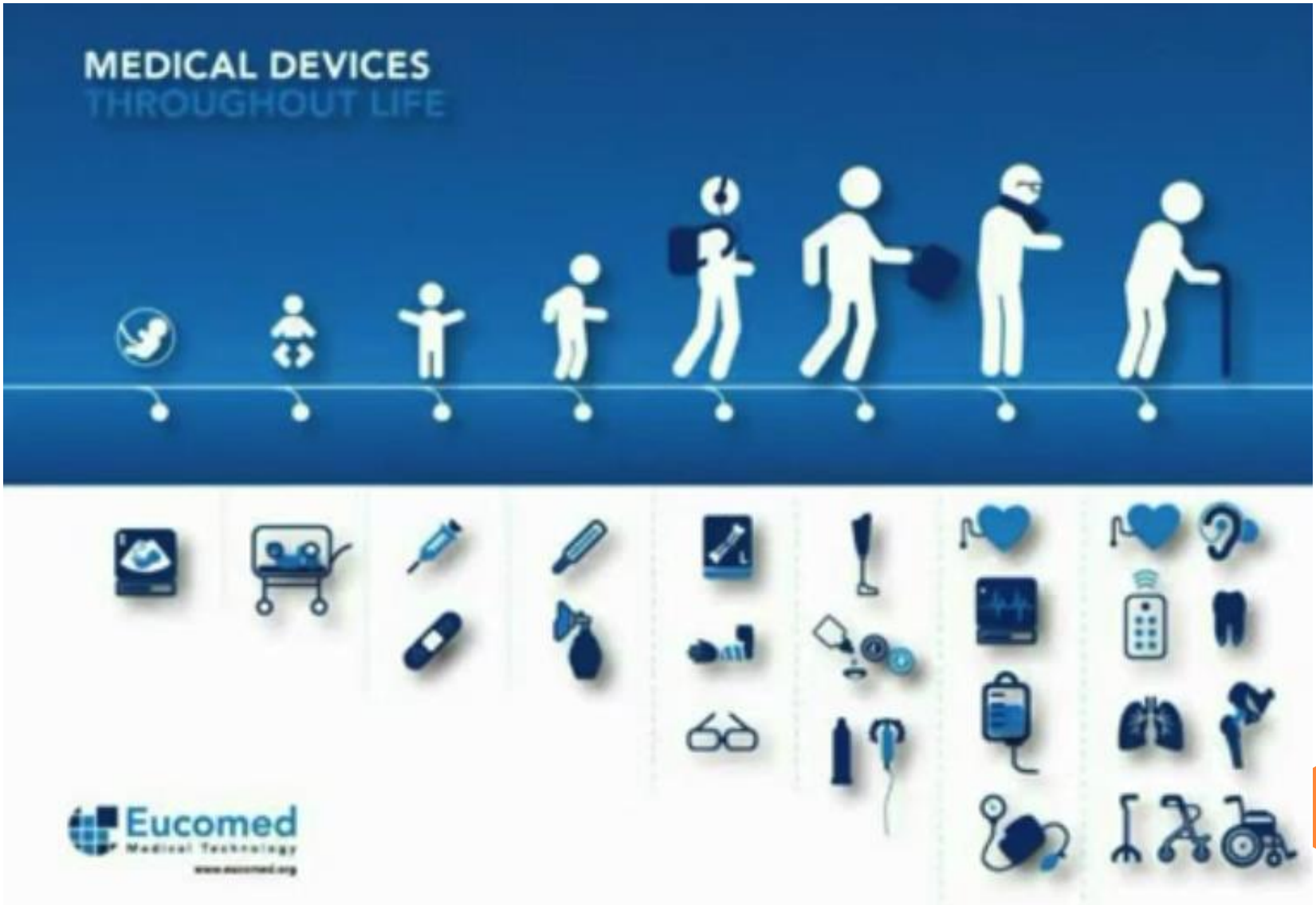
CAEB Lab. Website　http://caebserver.weebly.com/

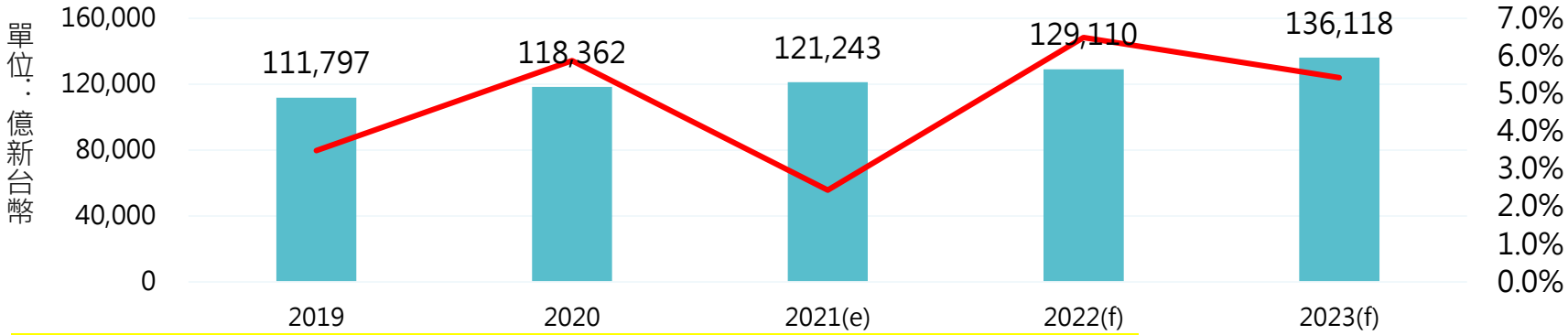
Outline

- 醫療器材簡介
- 3C (CAD\CAE\CAM)
  - Computer Aided Design
  - Computer Aided Engineering
  - Computer Aided Manufacture
- Medical Device Regulations for Implant
- 3R (RE\RP\RT)
  - Reverse Engineering
  - Rapid Prototyping (3D-printing)
  - Rapid Tooling

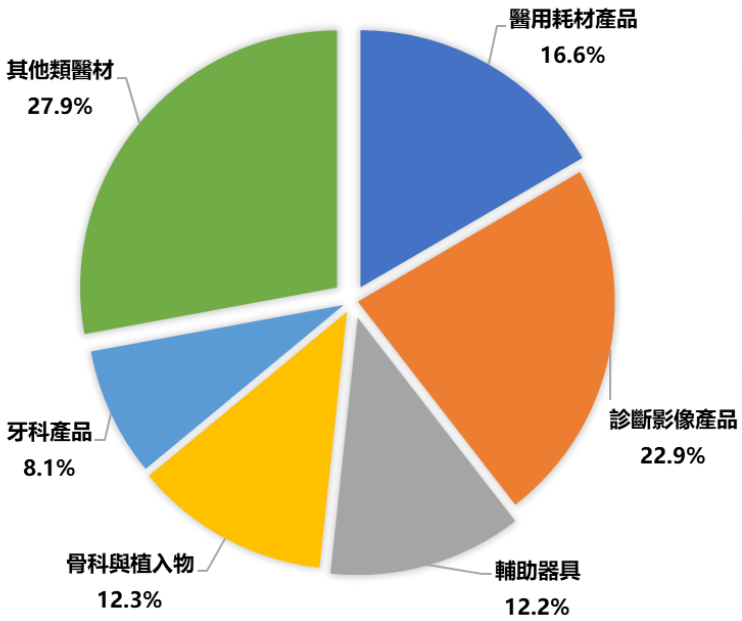
醫療器材重要性 (Importance of Medical Device)

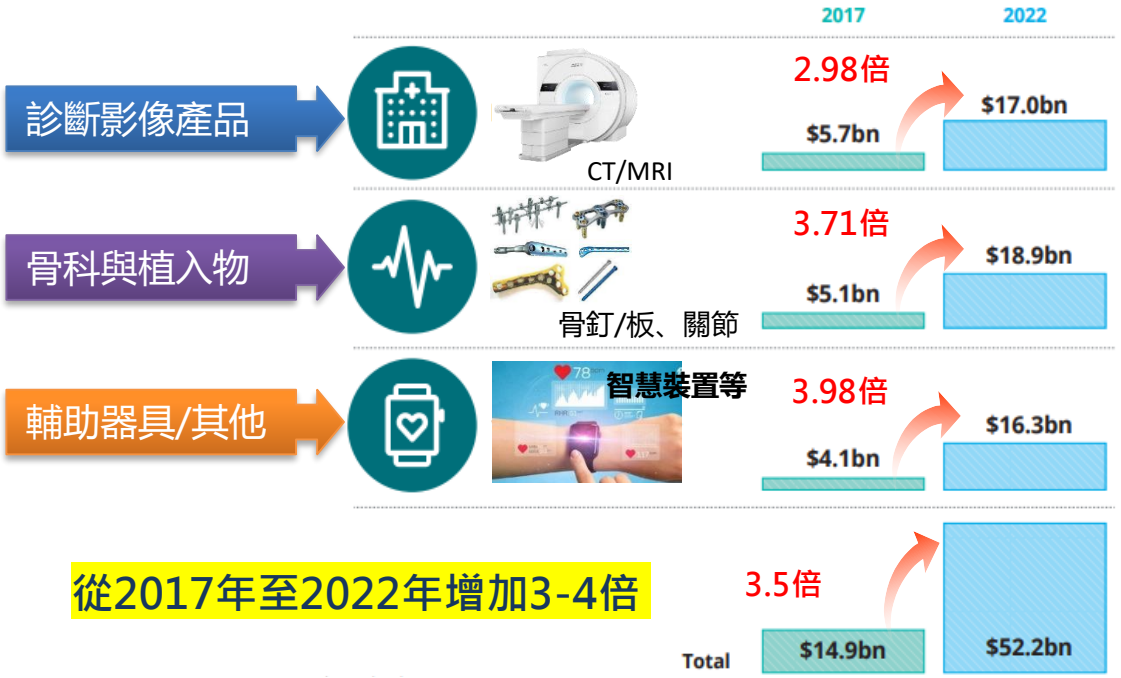


全球醫療器材市場產業概況



2023年全球醫材市場規模預計可達約13兆餘新臺幣(5000億美金)

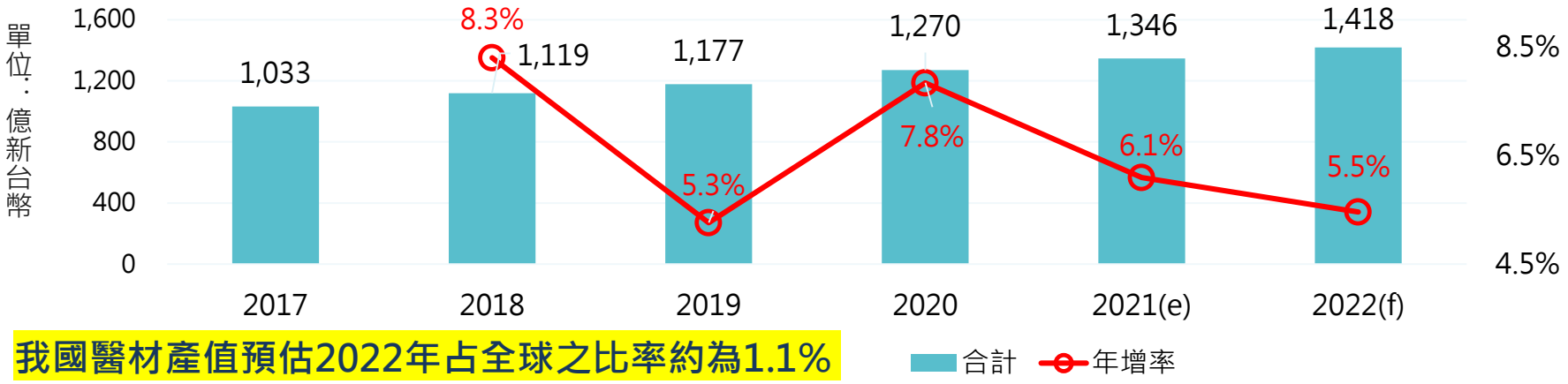




從2017年至2022年增加3-4倍

資料來源：BMI Research(2021/04)；工研院產科國際所(2021/05)

台灣醫療器材產業現況



我國醫材產值預估2022年占全球之比率約為1.1%

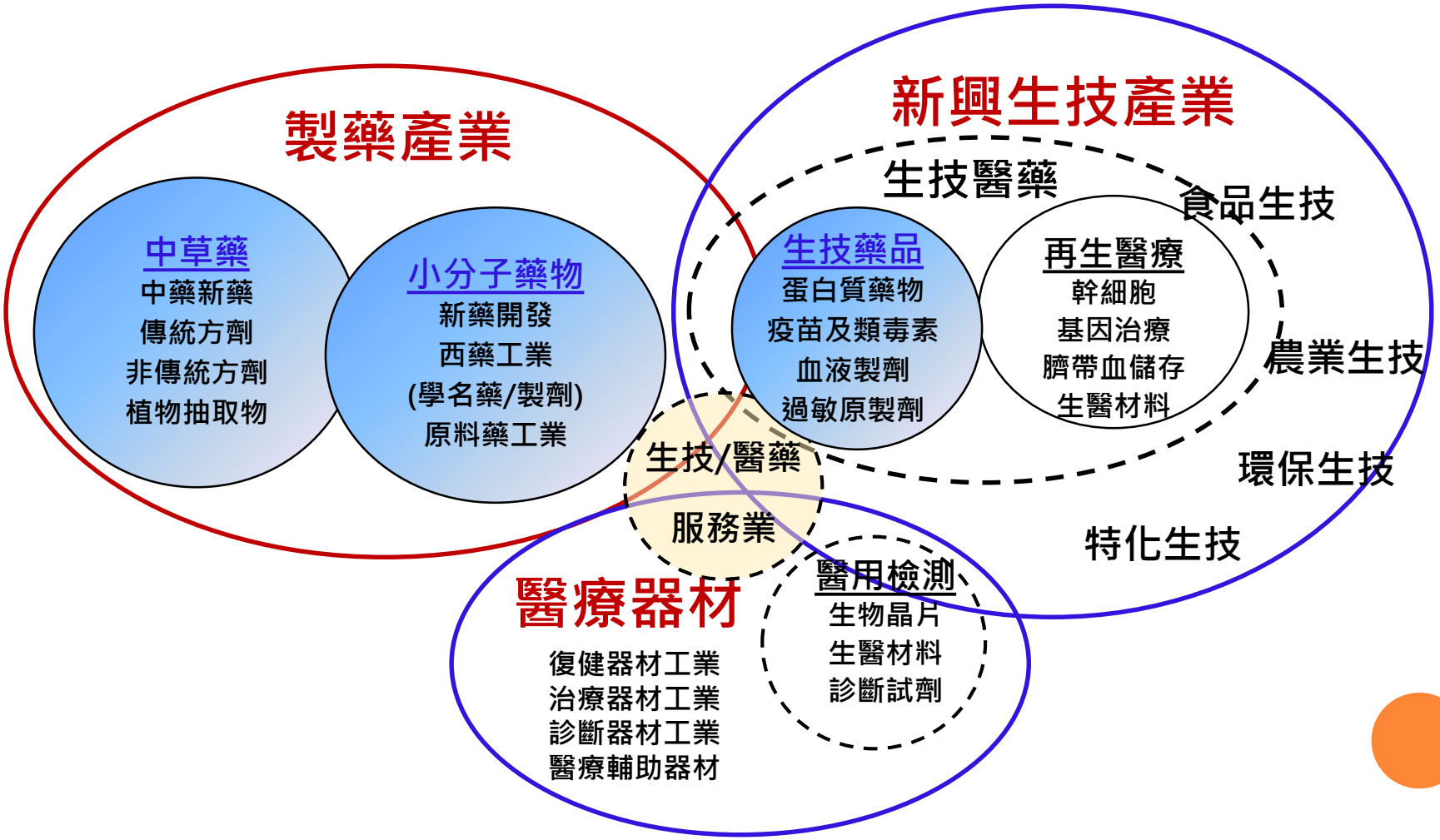
年度	年度通過張數	未註銷總張數	國產總張數	輸入總張數
2010	3,920	30,140	5,905	2010年產值662億(24億美元) 發出5,905張
2011	4,047	33,865	6,857	
2012	3,592	32,821	7,057	25,764
2013	3,827	35,705	8,079	27,626
2014	3,605	37,967	8,952	29,015
2015	3,743	40,579	9,678	30,901
2016	3,818	43,328	10,329	32,999
2017	3,940	46,797	11,203	35,594
2018	3,985	45,890	11,172	34,718
2019	3,770	45,839	11,332	2019年產值1,177億(43億美元) 發出11,332張

產值成長1.77倍
許可證成長1.91倍

2010年到2019年，10年間產值和發放許可證張數皆成長為近2倍

台灣生物科技產業現況-多元化發展

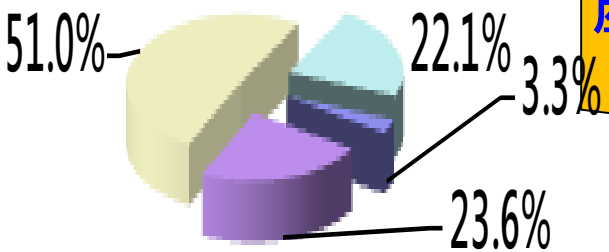
生技產業範疇



全球vs台灣醫療器材市場

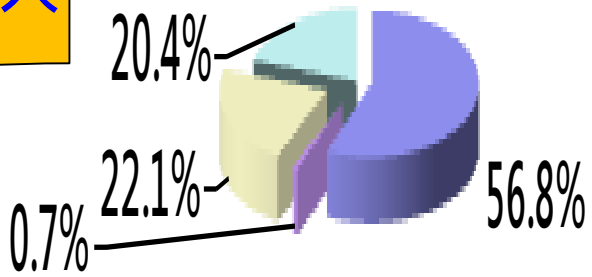
資料來源：金屬工業研究中心 ITRI-IEK (2008.3)

全球醫療器材市場



產業結構差異甚大

台灣醫療器材市場



居家用消費行醫材：台灣56.8% vs. 全球 3.3%

醫院用診斷監測設備：台灣0.7% vs. 全球 23.6%

醫院醫療用產品：台灣22 % vs. 全球 51.0%

- 居家用消費型醫材：輪椅、代步車、血壓計、體溫計、血糖計等。
- 醫院用診斷監測設備：X光儀器設備、心電圖、超音波、MRI、生理監視器等。
- 醫院治療用產品：牙科、眼科與骨科儀器設備、手術器械、骨科與牙科彌補物等。
- 耗材：手套、注射器與導管、急救箱、包紮敷料等。

目前台灣醫材產業，逐漸由居家用醫材，轉換為高階醫材(較高風險)發展，企圖有效提升醫材產值與市場佔有率。

法源依據

- 依據「醫療器材管理法」第3條第2項規定。

第三條	1	本法所稱醫療器材，指儀器、器械、用具、物質、軟體、體外診 斷試劑及其相關物品，其設計及使用係以藥理、免疫、代謝或化學以外之方法作用於人體，而達成下列主要功能之一者： 一、診斷、治療、緩解或直接預防人類疾病。 二、調節或改善人體結構及機能。 三、調節生育。
	2	**前項醫療器材之分類、風險分級、品項、判定原則及其他相關事項之辦法，由中央主管機關定之。**
	3	第一項第二款屬非侵入性、無危害人體健康之虞及使用時毋需醫事人員協助之輔具，得報請中央主管機關核准，免列為前項醫療器材之品項。
	4	前項輔具係指協助身心障礙者改善或維護身體功能、構造，促進活動及參與，或便利其照顧者照顧之裝置、設備、儀器及軟體等產品。

- **110年4月26日公告訂定「醫療器材分類分級管理辦法」，全文共7條。**

醫療器材分類品項

醫療器材管理辦法第3條

- 醫療器材依據功能、用途、使用方法及工作原理，分17類

一、臨床化學及臨床毒理學。
二、血液學及病理學。
三、免疫學及微生物學。
四、麻醉學。
五、心臟血管醫學。
六、牙科學。
七、耳鼻喉科學。
八、胃腸病科學及泌尿科學。
九、一般及整形外科手術。
十、一般醫院及個人使用裝置。
十一、神經科學。
十二、婦產科學。
十三、眼科學。
十四、骨科學。
十五、物理醫學科學。
十六、放射學科學。
十七、其他經中央衛生主管機關認定者。

- 前項醫療器材之分類分級品項如附件一。

醫療器材分類分級/風險

	台灣	美國	歐盟 (GHTF)	中國
範圍	試劑+儀器	試劑+儀器	試劑+儀器	試劑+儀器
分類	Class1 低 Class2 ↓ Class3 高	Class1 低 Class2(510k) ↓ Class3 高	List A 高 List B ↑ Self-test other 低	Class1 低 Class2 ↓ Class3 高
主管	TFDA	FDA	CA	SFDA
審查	TFDA(ITIR)	FDA Accerdited person	Notified body	C1市級 C2省級 C3國家級 境外 國家級
發證	TFDA	FDA	Notified body	C1市級 C2省級 C3國家級 境外 國家級

台灣醫療器材分類分級

醫療器材管理辦法第2條 醫療器材字號：衛部醫器製壹字第005

- 醫療器材依據風險程度，分成下列等級：
  - 第一等級：低風險性。
  - 第二等級：中風險性。
  - 第三等級：高風險性。

Class I	・如手動聽診器、醫用口罩、紗布、一般手術手動器械、彈性繃帶、壓舌板、機械式輪椅、矯正鏡片
Class II	・如衛生套、衛生棉條、輸液幫浦、靜電器(電位治療器)、動力式輪椅、軟式隱形眼鏡及其保存用產品、注射針筒/針頭、血糖機、血壓計、電子體溫計、磁振診斷裝置、外科及皮膚科用雷射儀、電子聽診器
Class III	・如心臟瓣膜置換物、人工水晶體、眼科用準分子雷射系統、冠狀動脈支架、心律調節器、人工牙根、玻尿酸植入物

醫療器材內容與查詢

西藥、醫療器材、化粧品許可證查詢

詳細處方成分 | 藥物外觀 | 仿單/外盒資料 | 授權使用 | 健保藥價查詢 | 離 開

許可證詳細內容

＊＊＊ 衛部醫器輸壹字第016710號 ＊＊＊

註銷狀態		註銷日期	
註銷理由		製造許可登錄編號	
有效日期	110/06/28	發證日期	105/06/28
許可證種類	醫　器		
舊證字號		醫療器材級數	第一等級
通關簽審文件編號	DHA09401671001		
中文品名	"貝格" 法西歐手術導板 (未滅菌)		
英文品名	"Bego" VarseoWax Surgical Guide (Non-Sterile)		
效能	限醫療器材管理辦法「牙齒骨內植入物附件(F.3980)」第一等級鑑別範圍。		
醫器規格	空白		
劑型		包裝	
標籤、仿單及包裝加註			
醫器主類別一	F牙科裝置	醫器次類別一	F3980牙齒骨內植
醫器主類別二		醫器次類別二	
醫器主類別三		醫器次類別三	
主成分略述			
限制項目	02輸　入		
申請商名稱	620118G125 新丞貿易有限公司		
申請商地址	台北市中正區南昌路1段157號3樓		

主製造廠

製造廠名稱	M471287000 BEGO Bremer Goldschlagerei-Wilh. Herbst GmbH & Co. KG		
製造廠廠址	Wilhelm-Herbst-Str. 1, 28359 Bremen, Germany		
製造廠公司地址			
製造廠國別	GERMANY	製程	

醫療器材分類品項

(共有 1739 筆資料,共分 174 頁,目前在第 1 頁)

序號	分類分級代碼▼	中文名稱▼	英文名稱▼	等級▼
1	A.0001	苯環利定試驗系統	Phencyclidine test system	2
2	A.0002	臨床化學離子分析儀	Clinical chemistry electrolyte system	1
3	A.1020	酸性磷酸酶(總量或前列腺的)試驗系統	Acid phosphatase (total or prostatic) test system	2
4	A.1025	促腎上腺皮質荷爾蒙試驗系統	Adrenocorticotropic hormone (ACTH) test system	2
5	A.1030	丙胺酸轉胺酶試驗系統	Alanine amino transferase (ALT/SGPT) test system	1
6	A.1035	白蛋白試驗系統	Albumin test system	2
7	A.1040	醛醇縮合酵素試驗系統	Aldolase test system	1
8	A.1045	醛類脂醇試驗系統	Aldosterone test system	2
9	A.1050	鹼性磷酸酶或同功酶試驗系統	Alkaline phosphatase or isoenzymes test system	2
10	A.1055	新生兒胺基酸、游離肉鹼及醯基肉鹼篩檢用串聯質譜儀系統	Newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry.	2

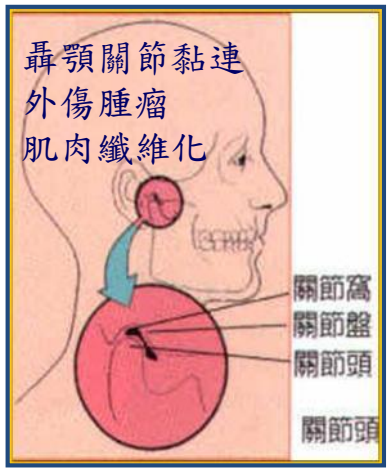
代碼	名稱	鑑別	等級
F.3640	骨內植體(Endosseous implant)	骨內植體(endosseous implant)－是由如鈦金屬製成的器材，以手術方式放置於上或下頜牙弓的骨骼內以提供對修復器材，如人工牙齒之支撐及恢復患者的咀嚼功能。	3

US FDA 分類醫療器材 (Taiwan TFDA)

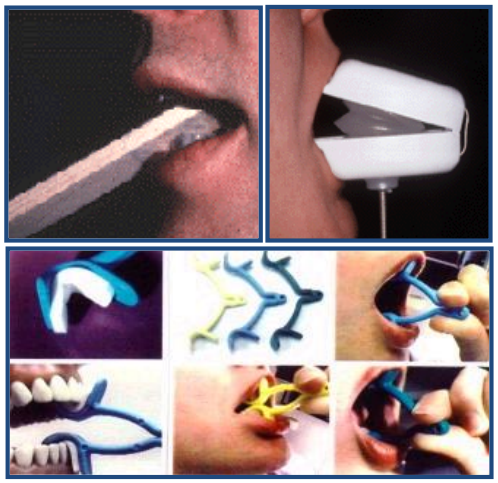
- **Class I:** simple, low risk devices
  - General control to ensure safety and effectiveness
  - Mostly exempt from Premarket Notification [510(k)]
- **Class II:** more complex, moderate risk devices
  - General control and Special control
  - Require 510(k) → Substantial Equivalence (as safe and effective as legally marketed device, SE)
- **Class III:** most complex, highest risk devices
  - General control
  - Premarket Approval (PMA) → Safety & Effectiveness

Low risk medical device development

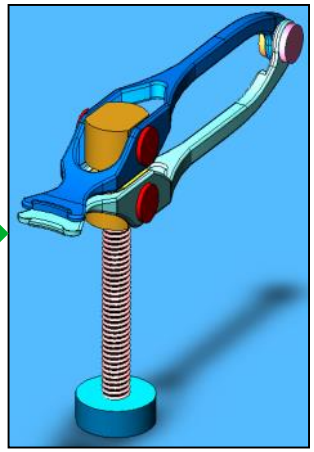
❖口腔開合運動復健器設計開發及臨床測試

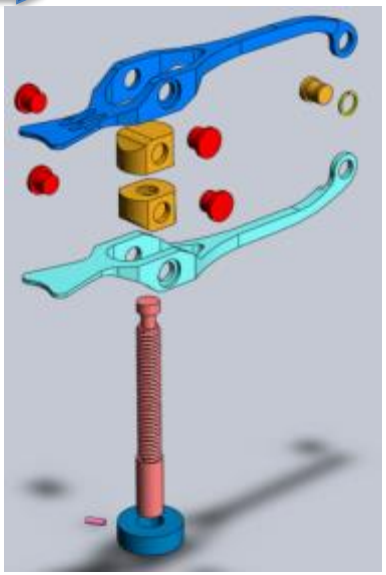


顳顎關節障礙



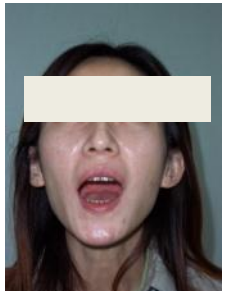
CAD

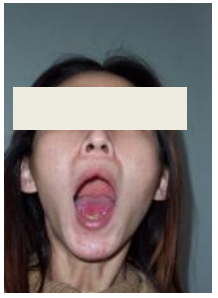


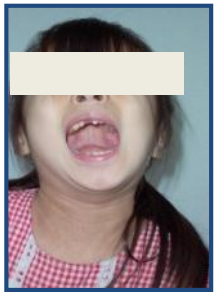


CAM

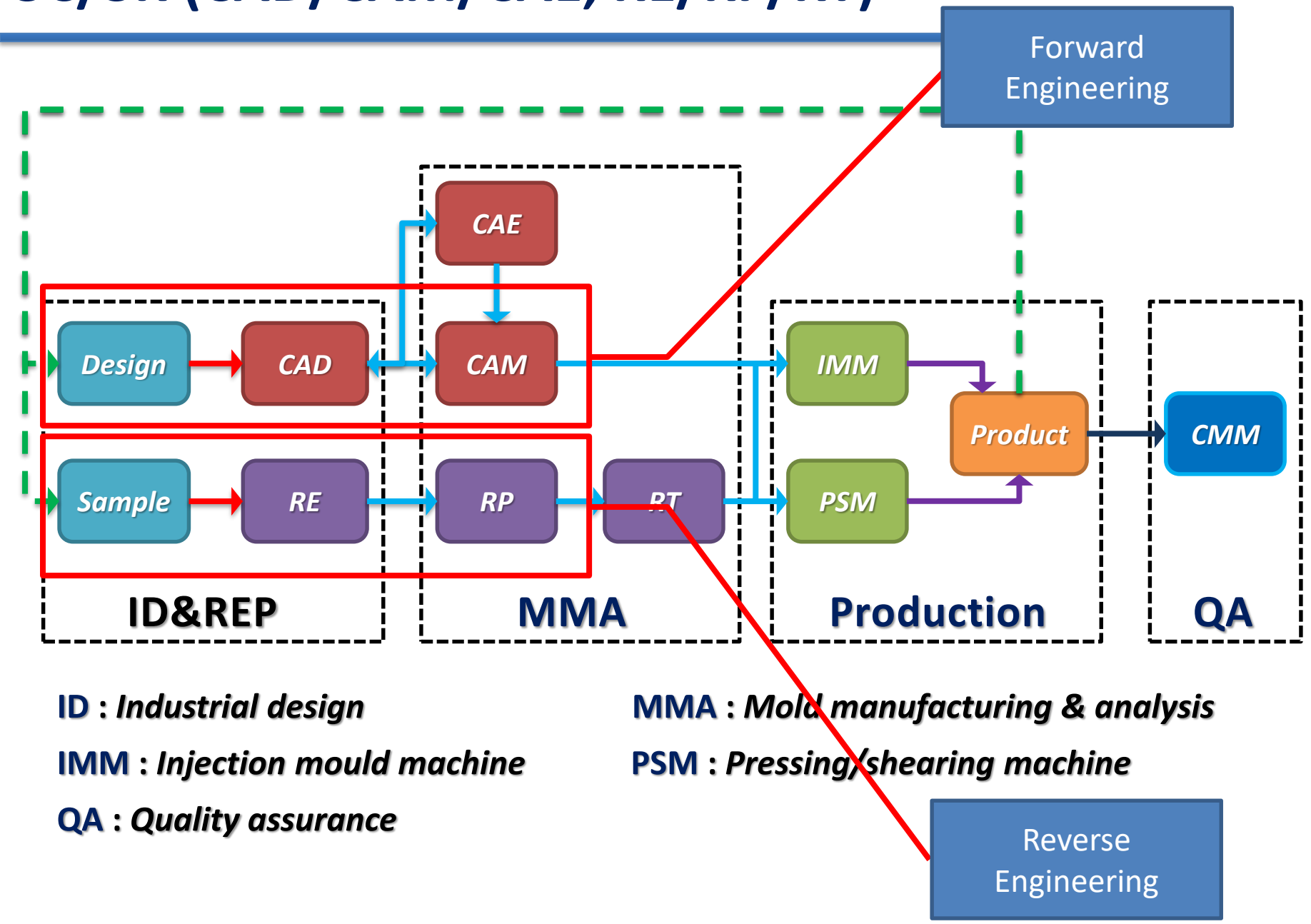
Clinical Test







3C/3R (CAD/CAM/CAE, RE/RP/RT)



ID : *Industrial design*

IMM : *Injection mould machine*

QA : *Quality assurance*

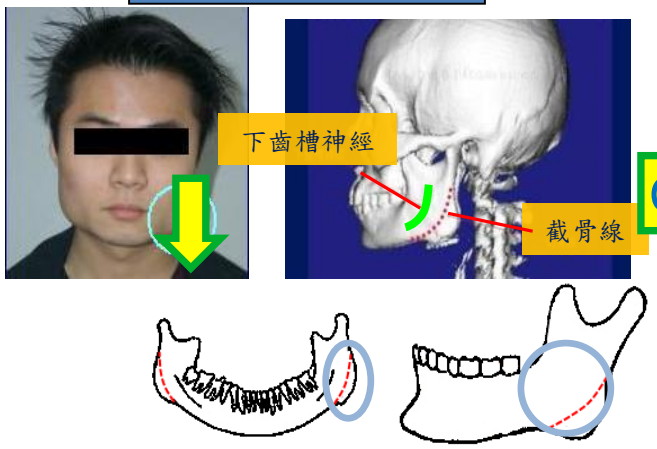
MMA : *Mold manufacturing & analysis*

PSM : *Pressing/shearing machine*

CAD/CAM clinical application

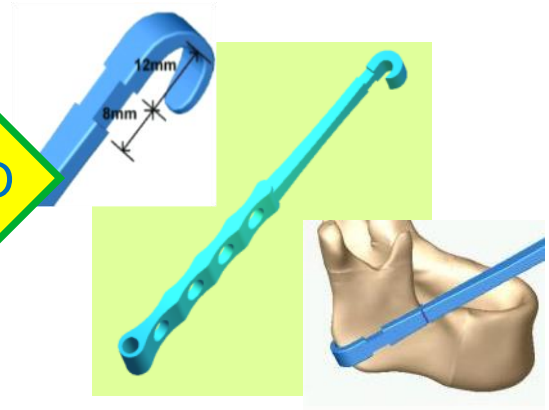
❖下頷角整形手術輔助器具設計

國字臉矯正手術

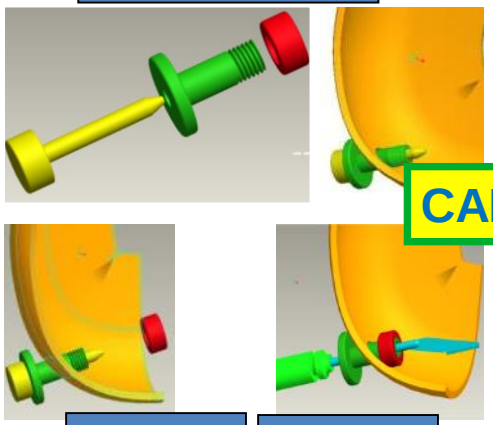


CAD

下頷角量測輔助器械



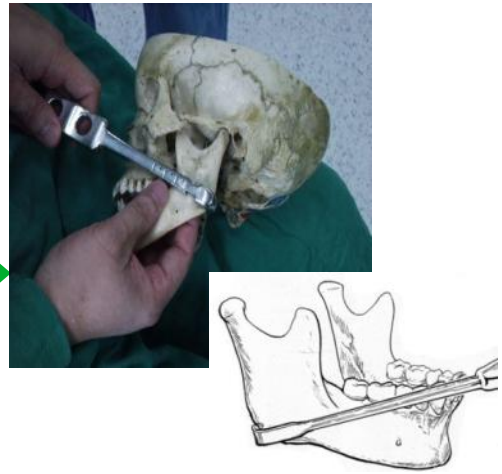
皮膚保護套



CAD

CAM

Clinical Test



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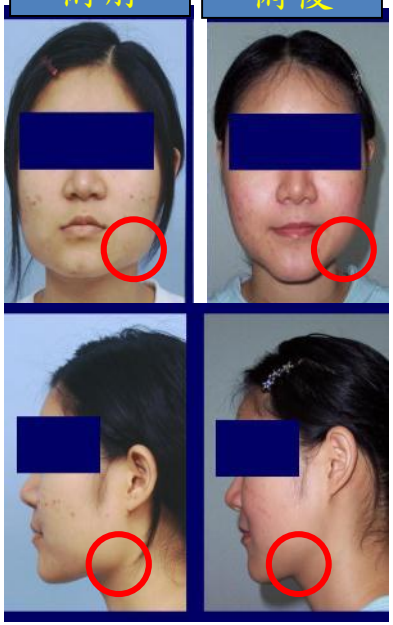
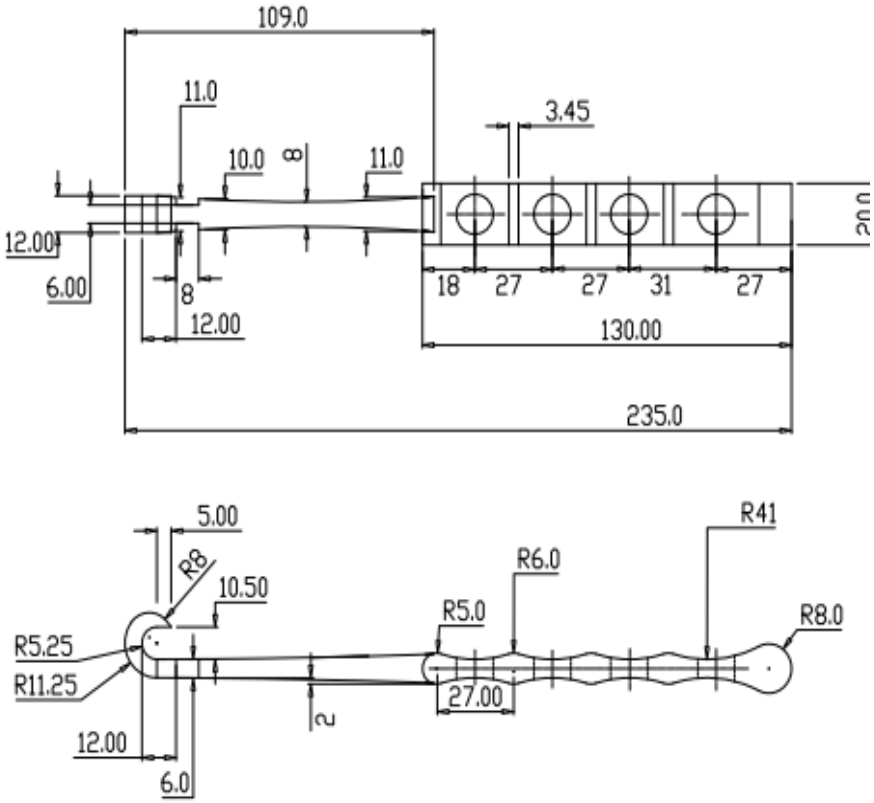
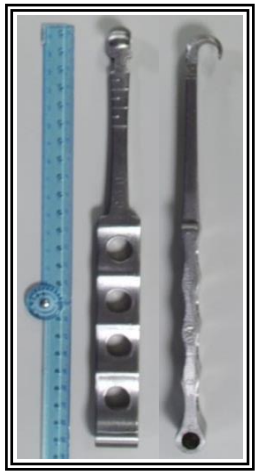


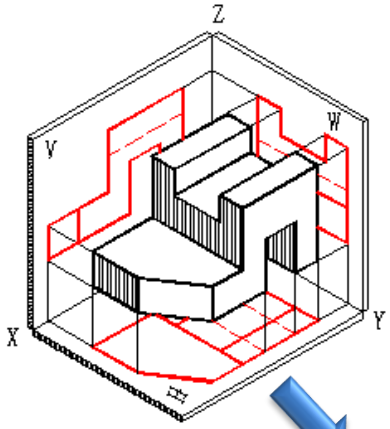
3C(CAD/CAM/CAE)

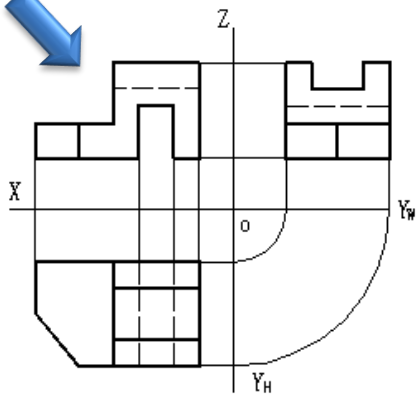
❖電腦輔助設計 (Computer Aided Design, CAD)

→運用工程圖學原理-應用幾何、正投影、剖視圖、尺度標註、公差、表面符號
→透過手繪(早期)或電腦軟體製圖 (AutoCAD)

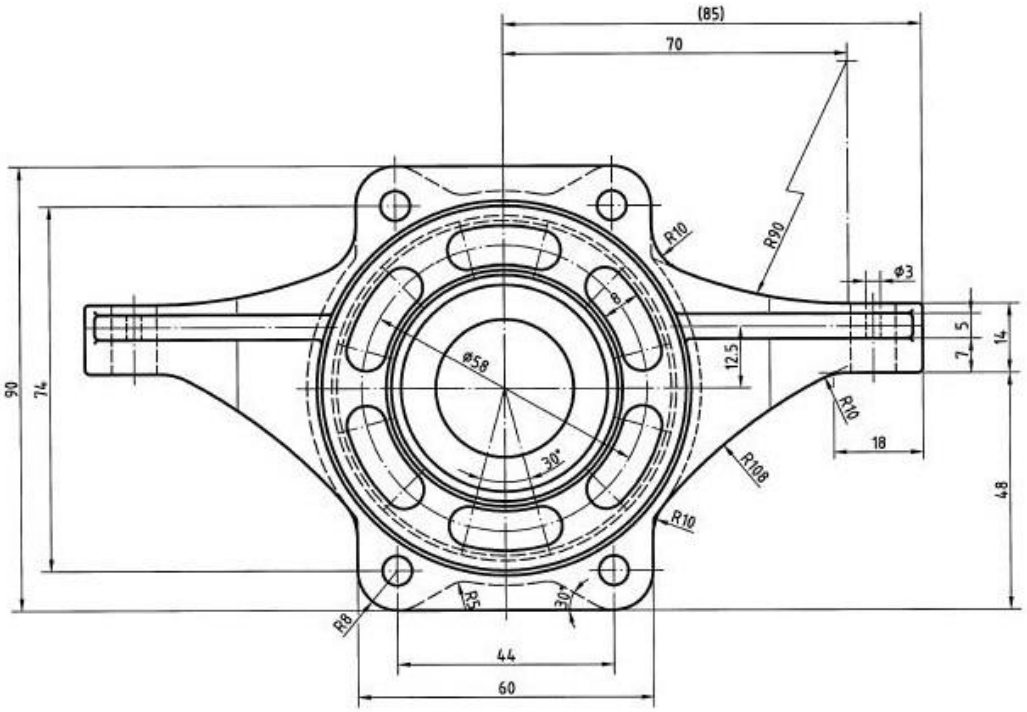




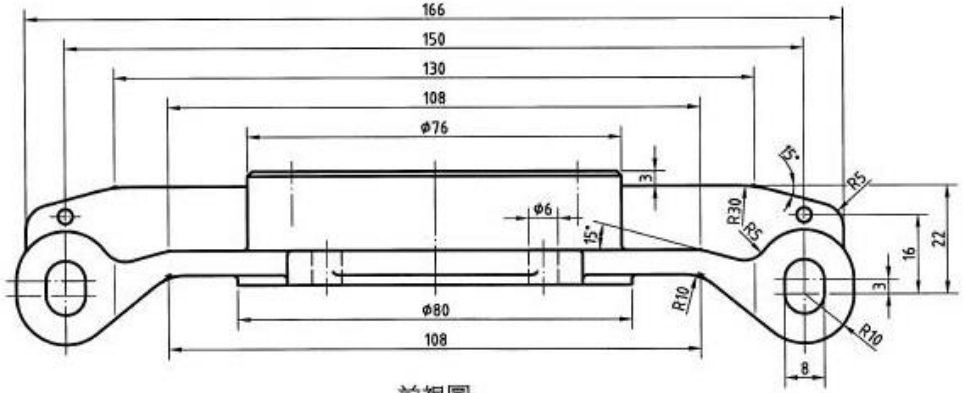




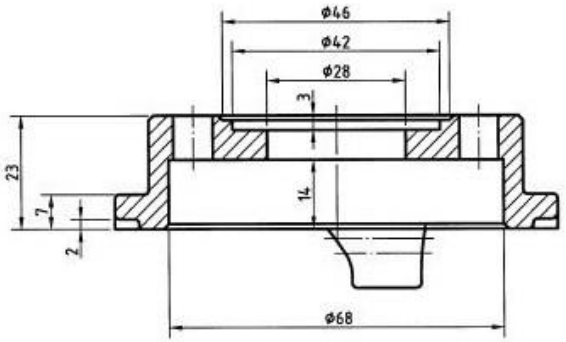
2D三視工程圖



未標註之圓角為R1
未標註之去角為1x45°



前視圖



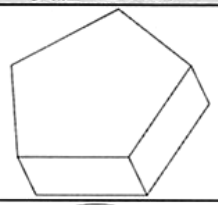
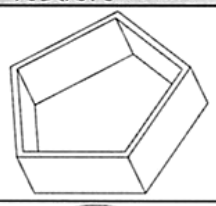
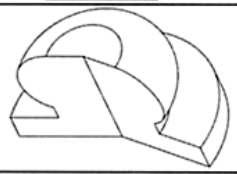
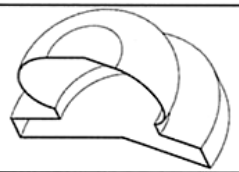
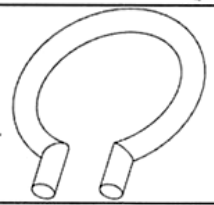
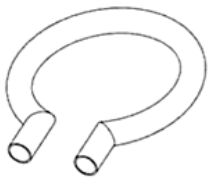
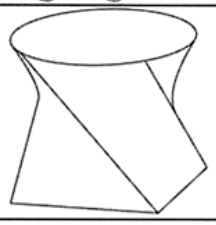
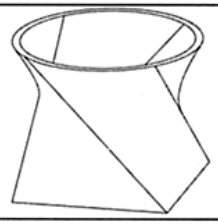
電腦輔助立體製圖	圖名	吊架盤		作圖時間		核定單位	行政院勞工委員會 中部辦公室	命題暨審查委員	康鳳梅,邱嘉佑,林瑞乾,柯金河,簡慶郎,邱永銘
丙級技術士技能檢定術科試題	比例	1：1	投影法	核定日期	91年12月			試題編號	152-910306

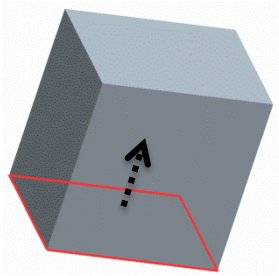
3C (CAD/CAM/CAE)

❖電腦輔助設計 (Computer Aided Design, CAD)

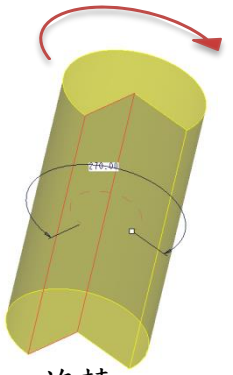
→運用電腦參數化軟體進行實體設計(Pro/Engineering、Solidworks)

→參數化繪圖原理採 “特徵”（Feature）為基礎之特性，利用一般自然的機械物件之觀念，如引伸、旋轉、掃瞄、導圓角、薄殼、鑽孔等，以最自然的思考方式從事設計工作。擺脫了傳統以點、線、面為主的系統架構，目前的3D CAD系統皆採用 “特徵”的原則。

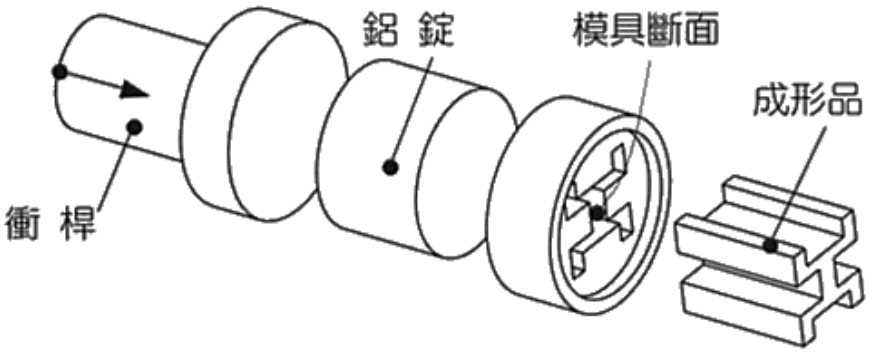
■長肉（加材料）-Protrusion		
	實體（Solid）	薄長薄肉（Thin）
引伸（Extrude）		
旋轉（Revolve）		
掃描（Sweep）		
混合（Blend）		



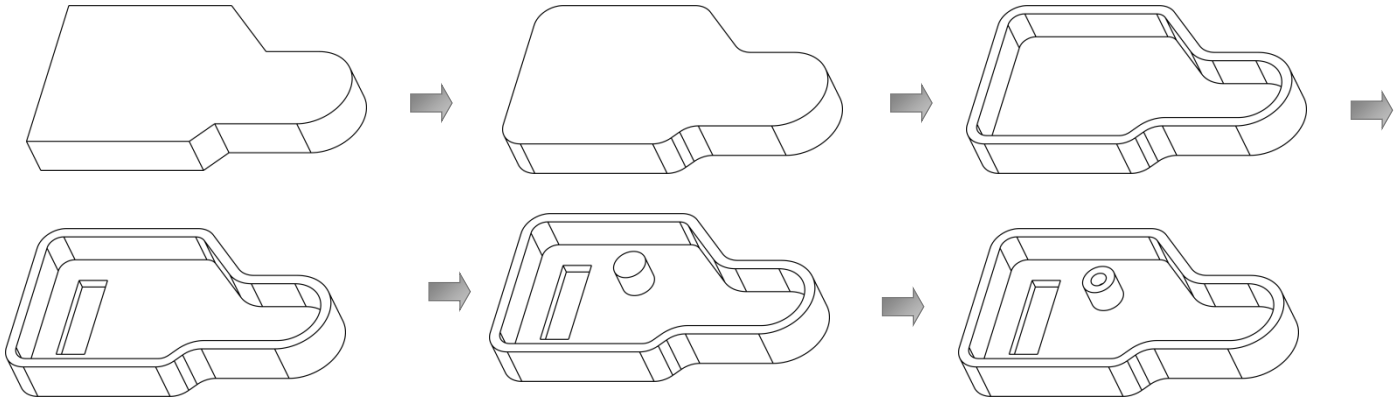
長出



旋轉

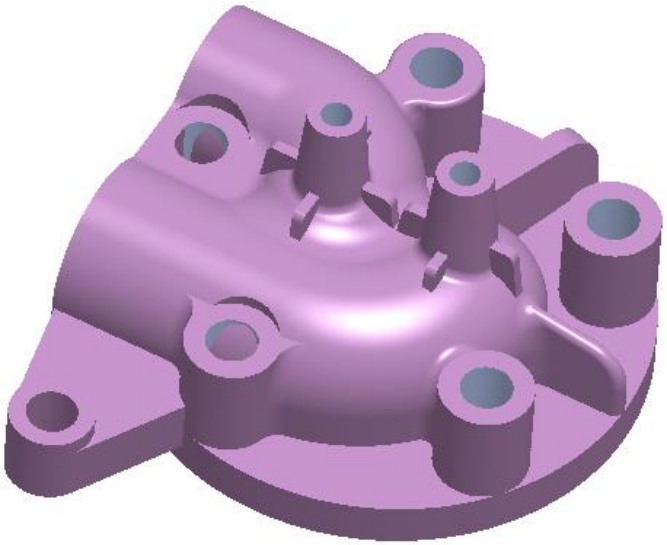


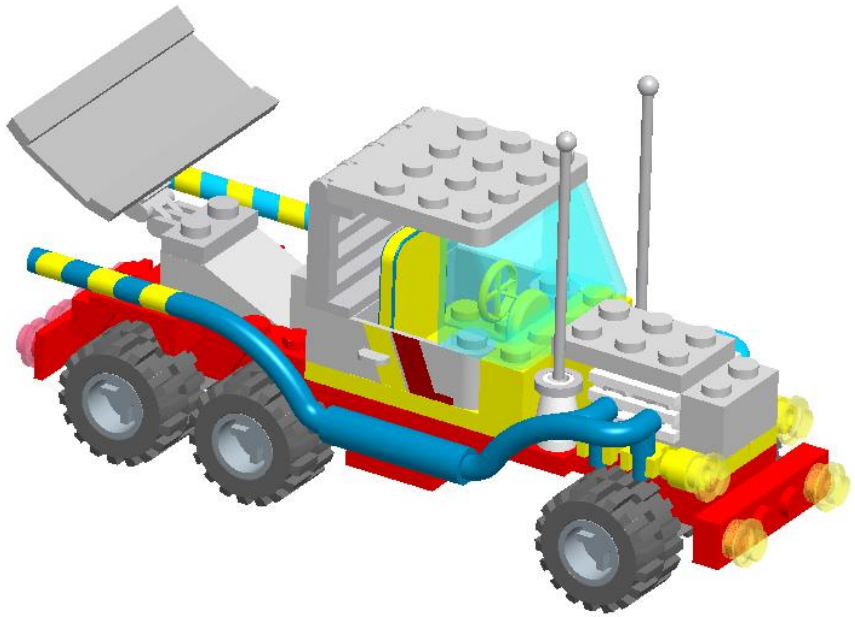
3C (CAD/CAM/CAE)



1個「零件」＝ 特徵1 ＋ 特徵2 ＋ 特徵3 ＋ … ＋ 特徵N

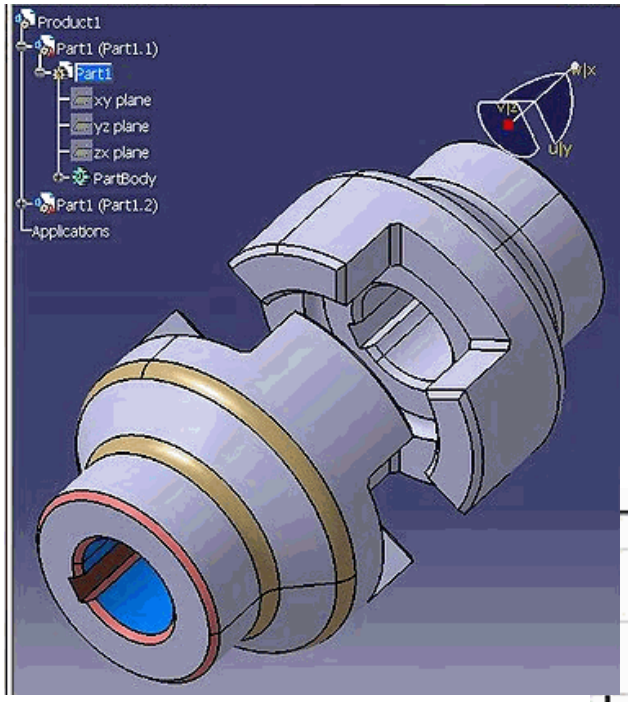
1個「組立件」＝ 零件1 ＋ 零件2 ＋ 零件3 ＋ … ＋ 零件N

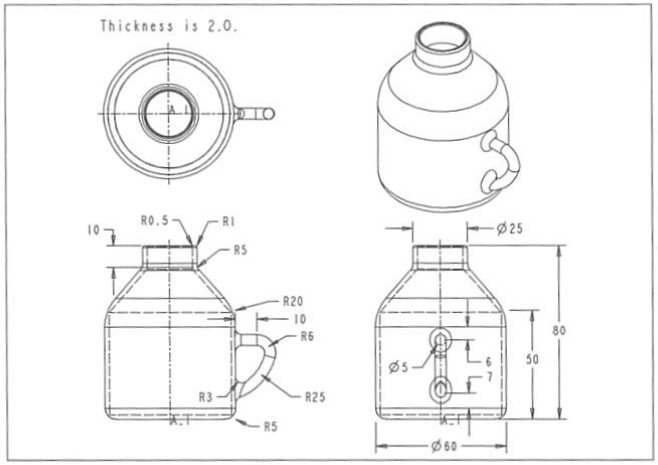


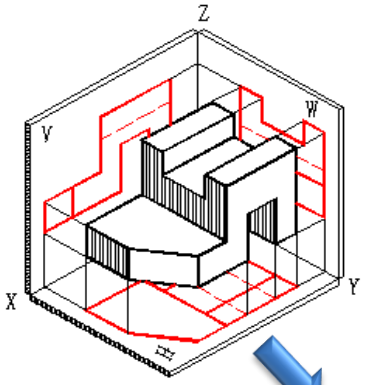


3C (CAD/CAM/CAE)

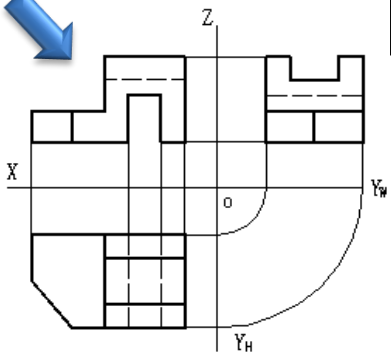
❖電腦輔助設計 (Computer Aided Design, CAD)



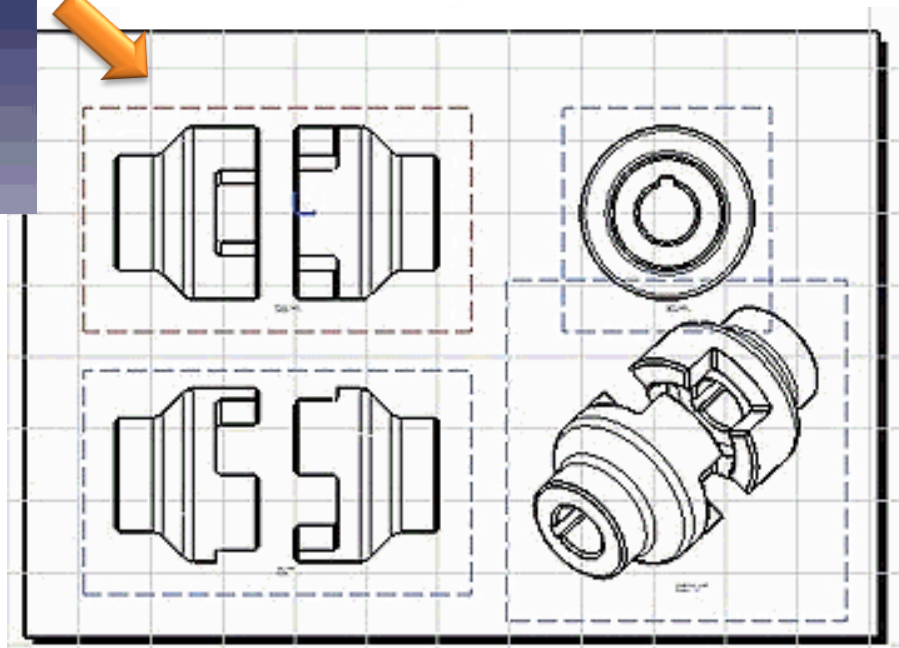




實體/模型

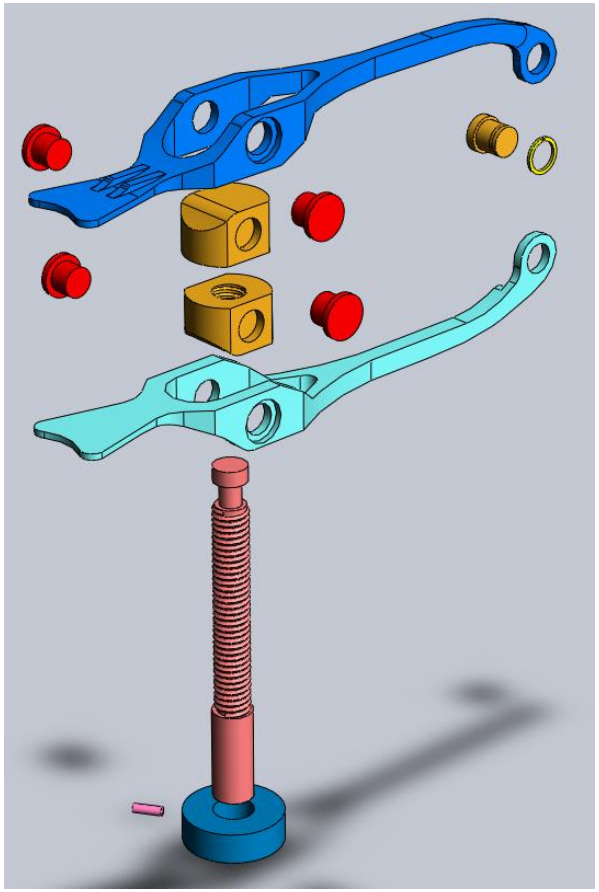


三視工程圖

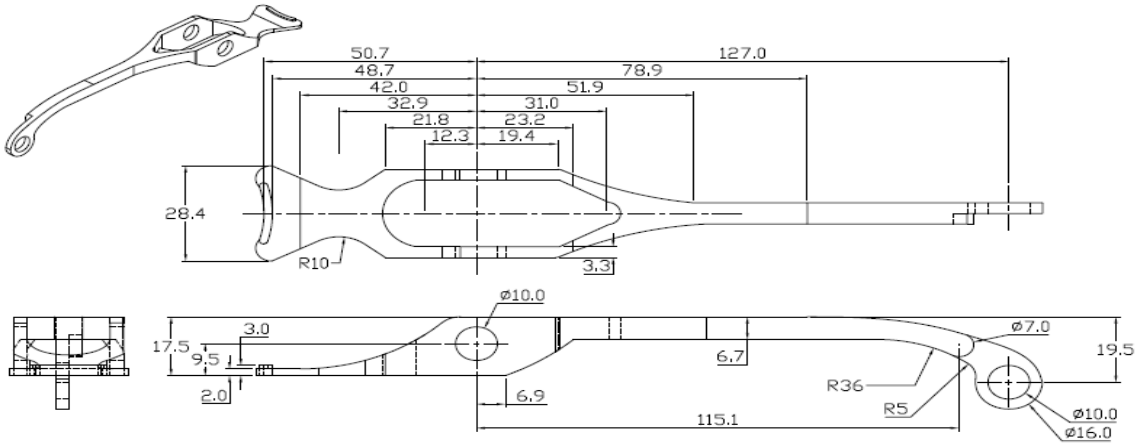


3C (CAD/CAM/CAE)

- ❖電腦輔助設計 (Computer Aided Design, CAD)
- ❖機構設計原理



3D 模型繪圖



2D三視工程圖

衛署衛署醫器製壹字第00394
世亨科技股份有限公司 (02)-29

行政院衛生署第一等級醫療器材許可證

中文名稱："世亨"一般手術用手動式器械(未滅菌)

英文名稱："SHI HENG" Manual Surgical Instrument for General Use(Non-Sterile)

類別：

藥商名稱：世亨科技股份有限公司

規格：空白

製造廠名稱：世亨科技股份有限公司

製造廠地址：

效能：

處方：空白。

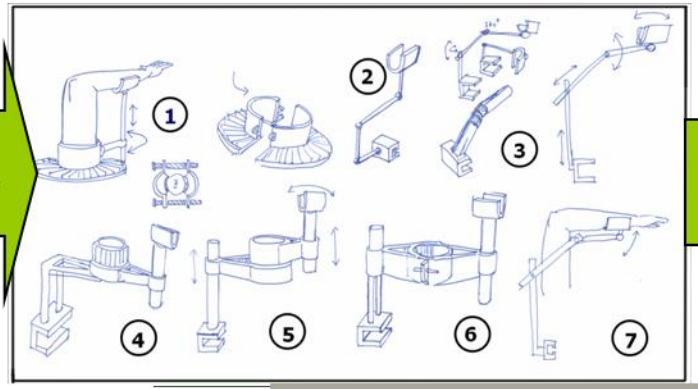
行政院衛生署署長

邱文達

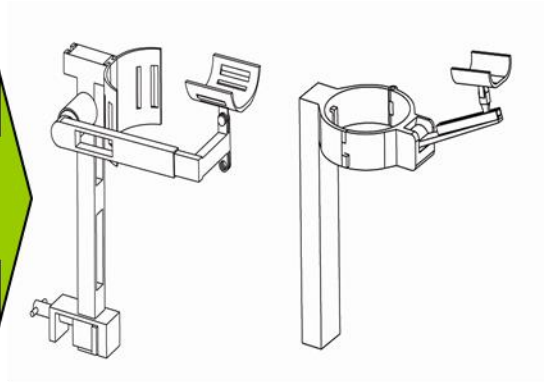
CAD/CAM clinical application

❖仰躺式肘關節手術輔助器械之設計與開發手肘

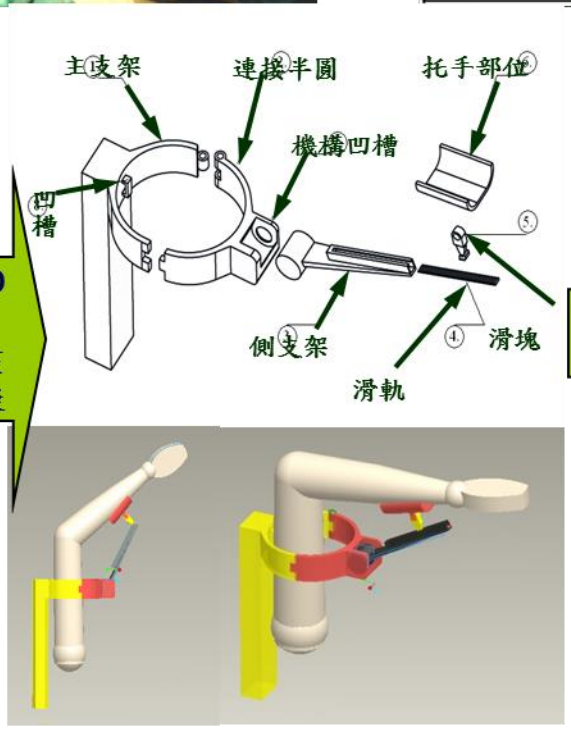
雛形機構設計



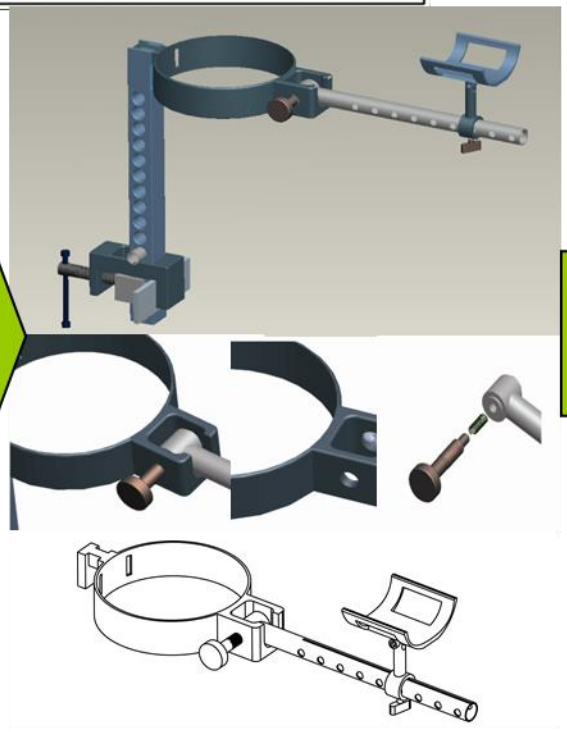
可行方案整合



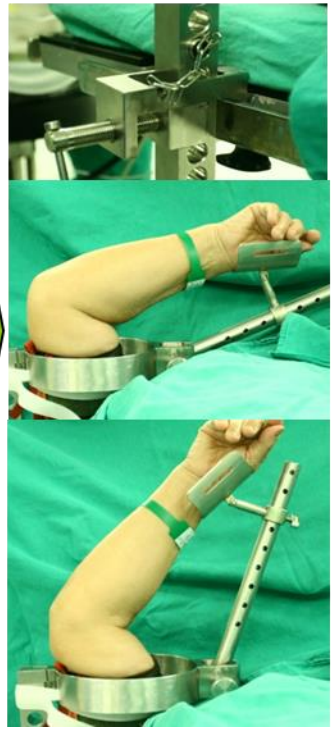
CAD及動畫模擬



機構模擬

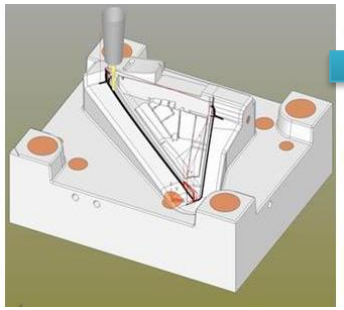


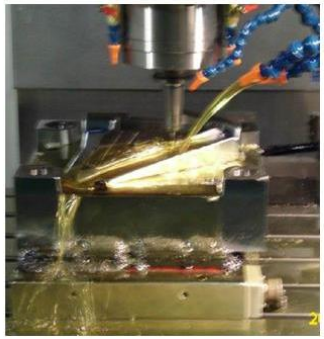
CAM及臨床測試



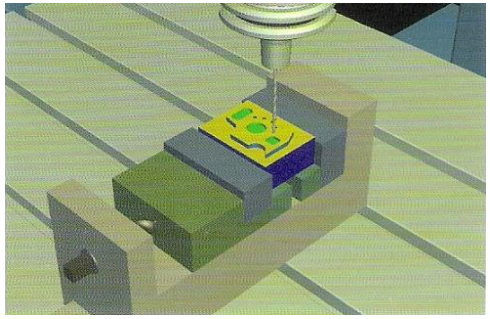
3C (CAD/CAM/CAE)

- 電腦輔助製造 CAM (Computer Aided Design)
  - CNC車铣床、複合切削機(3, 4, 5, 6軸) 、精度





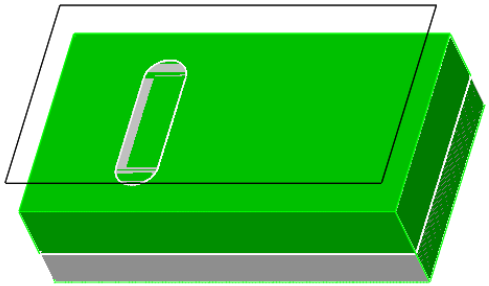
電腦製造路徑規劃

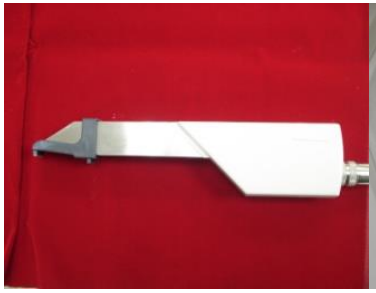


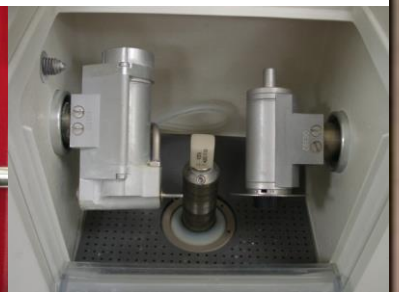
工具機

3C (CAD/CAM/CAE)

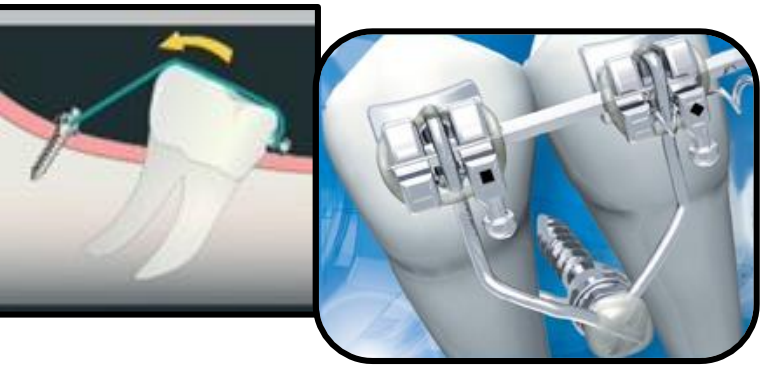
- 電腦輔助製造 CAM
  - CEREC (CAD/CAM)



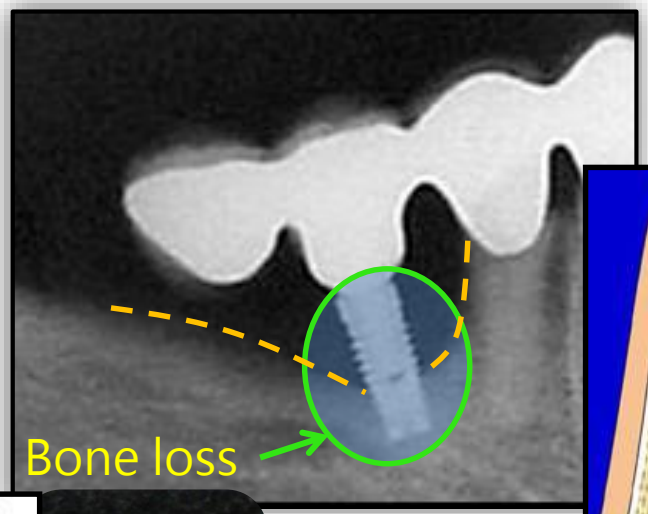


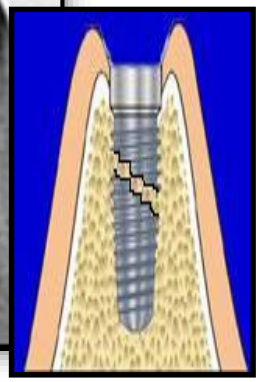


Dental Biomechanics

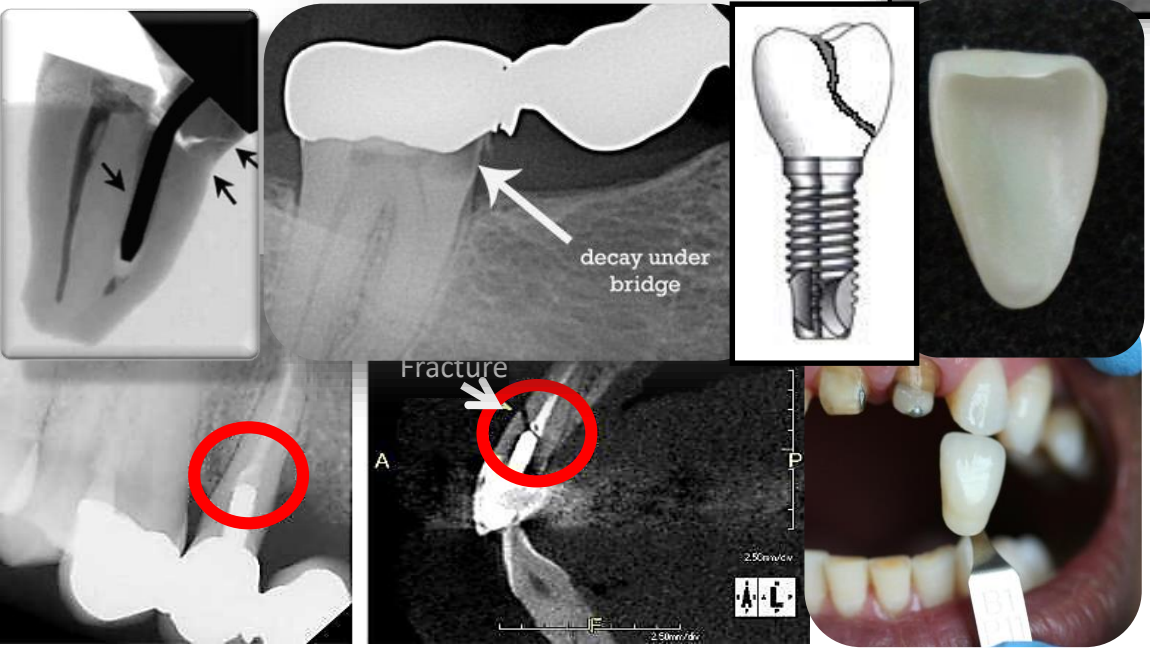


Orthodontic mini screw

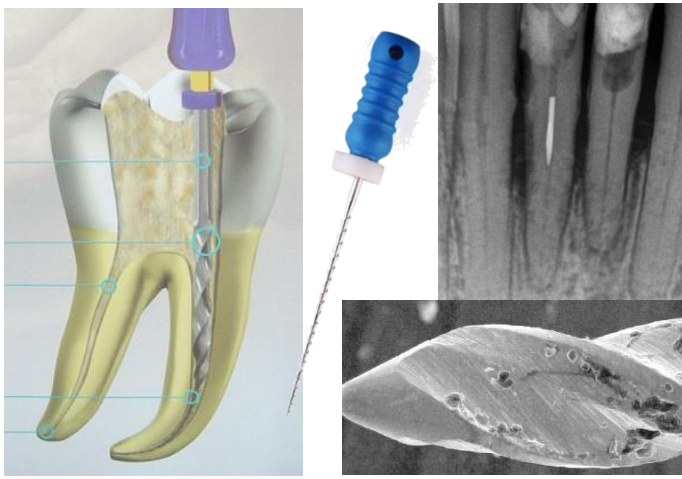




Dental implant



OD & Prosthetic



Endodontic

Moderate/High Risk Medical Devices

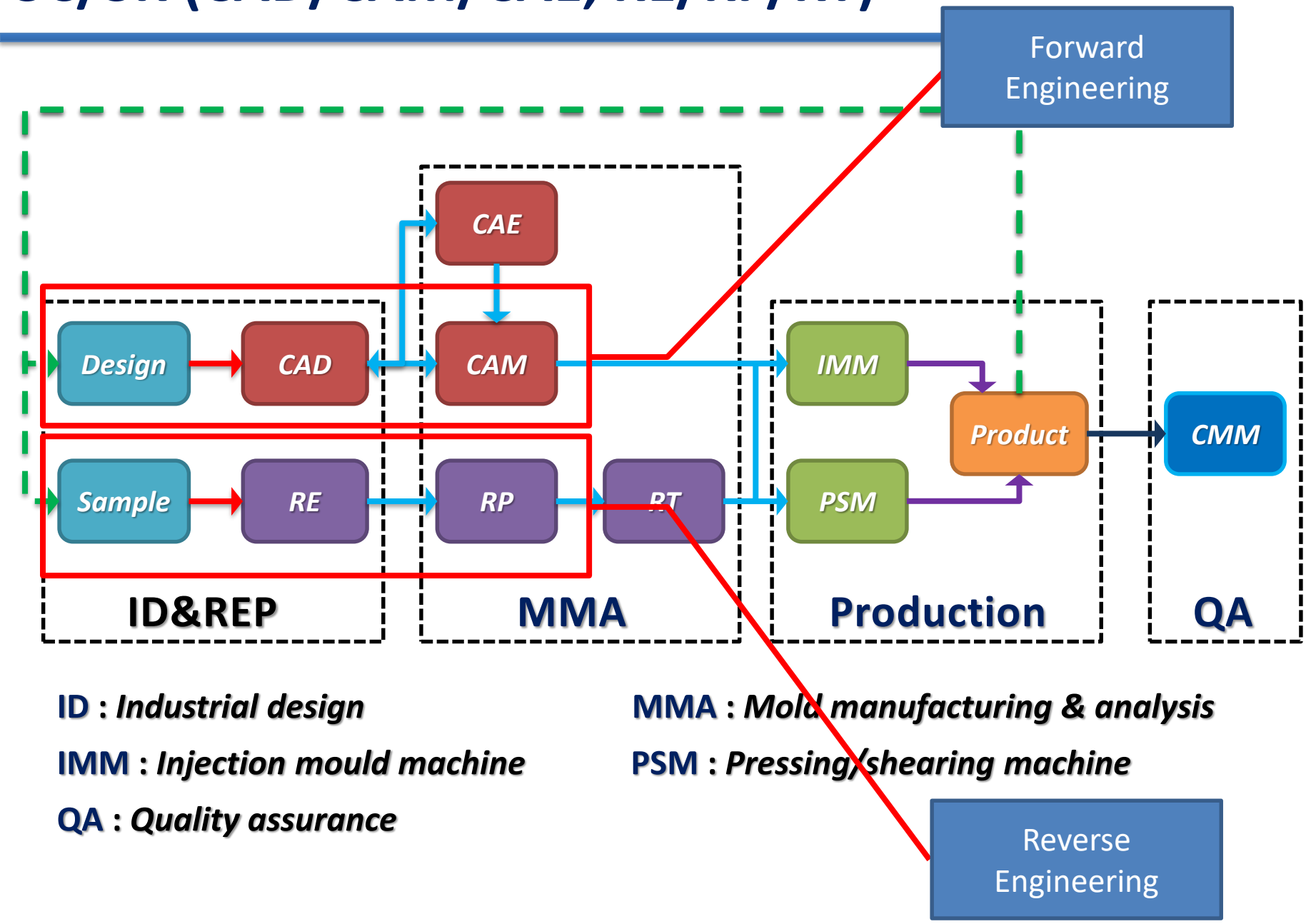
★安全 有效★

工業用螺絲

人工牙根

NT0.X→NTX0000

3C/3R (CAD/CAM/CAE, RE/RP/RT)



ID : *Industrial design*

IMM : *Injection mould machine*

QA : *Quality assurance*

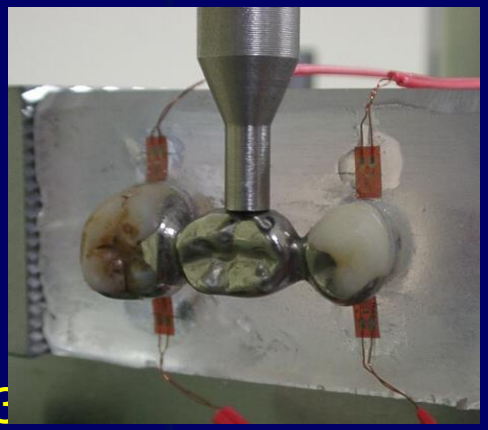
MMA : *Mold manufacturing & analysis*

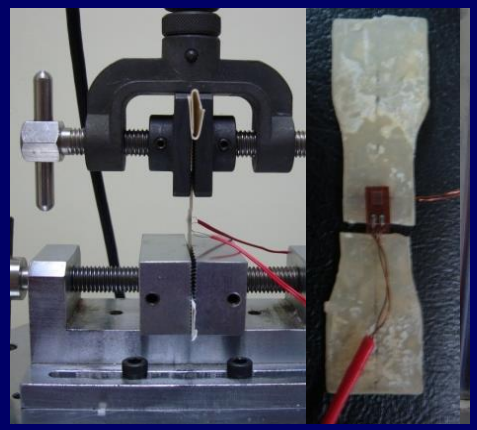
PSM : *Pressing/shearing machine*

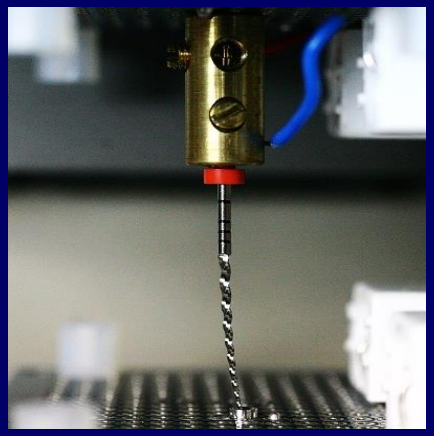
Computer aided engineering (CAE)

- **Biological and engineering aspects are suitable but difficult to evaluate by experimental techniques**
  - **limited information**
    - ***stress, strain, energy, etc.***
  - **variation within samples**
    - ***size, age, biochemical, morphologic, etc.***

- **Relevant biomechanical rationales still unclear**



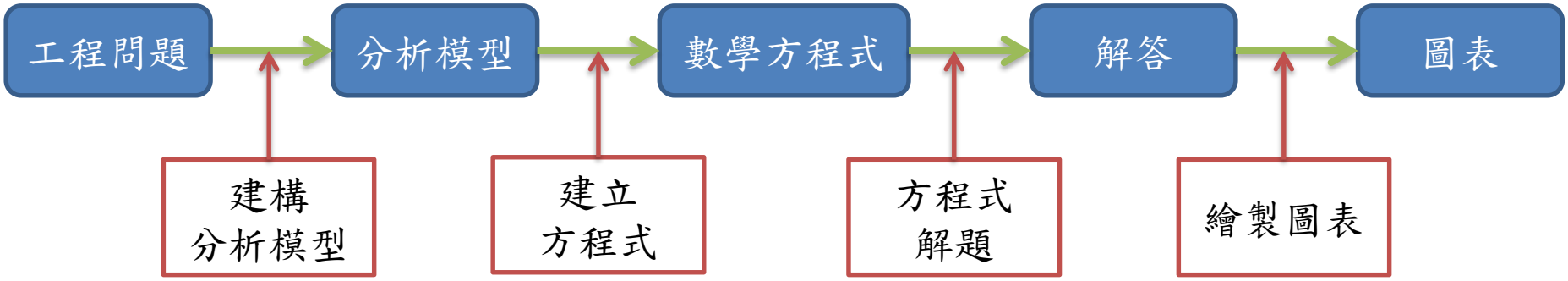


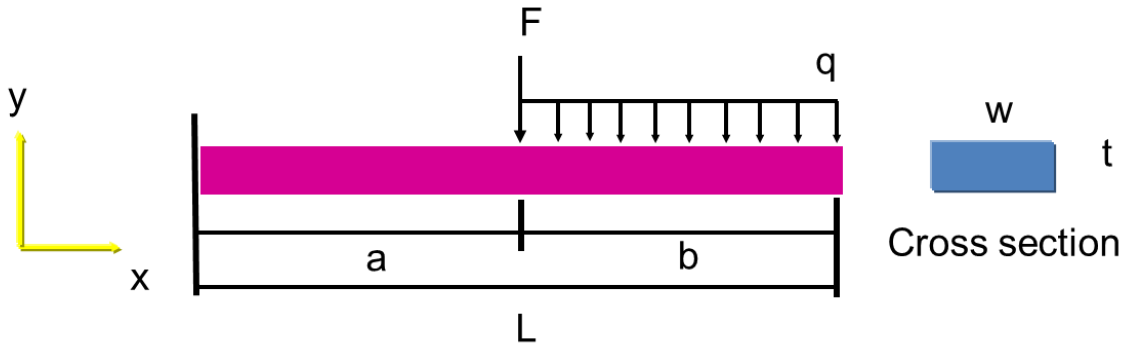


Computer Aided Engineering (CAE)

❖電腦輔助工程 (Computer Aided Engineering, CAE)

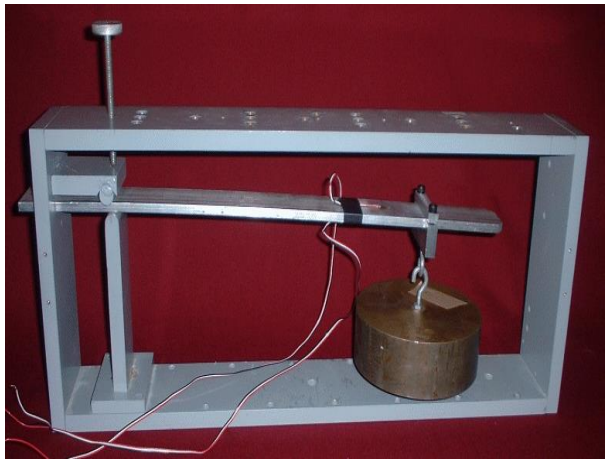
傳統工程分析





$$y=Fa^3(3L-a)/6EI+q(3L^4-4a^3L+a^4)/24EI$$

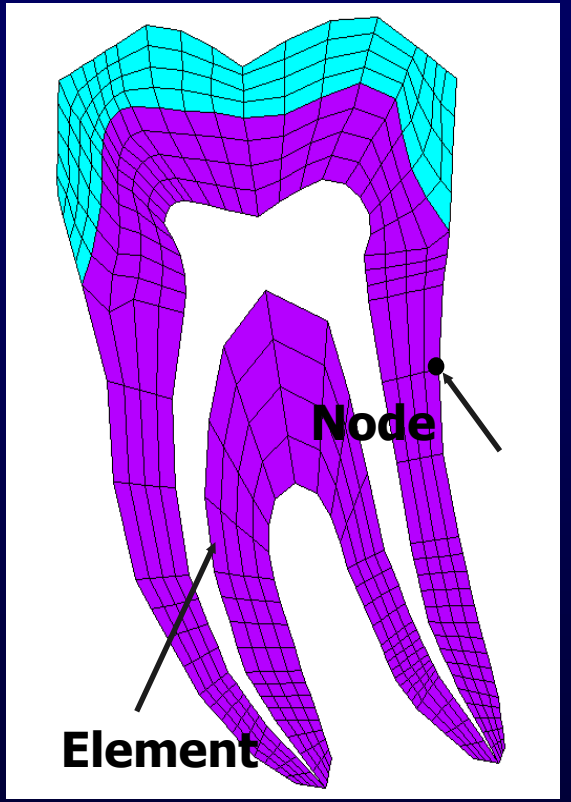
Analytical analysis



Experimental approach

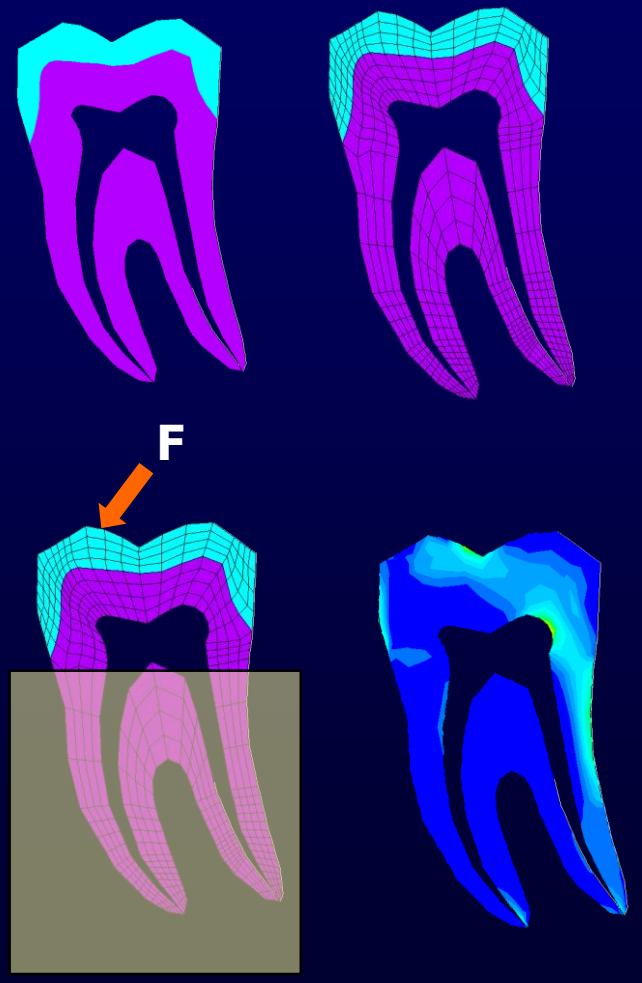
Computer aided engineering (CAE)

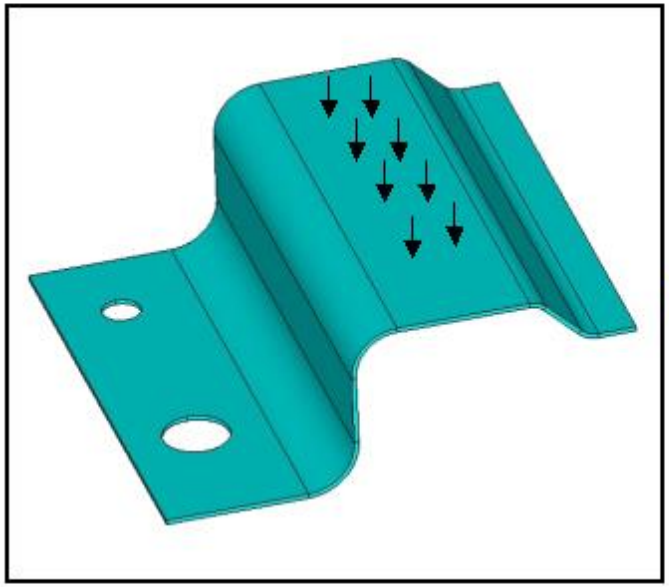
- **Fundamental concepts in FEM**
  - 實際的物理問題很難利用單一的微分方程式描述，更無法順利求其解析解(analytical solution)
  - 有限元素法的精神是將複雜的幾何外型的結構物體切割成許多簡單的幾何形狀稱之為元素(element)
  - 元素與元素間以“節點”(node)相連
  - 由於元素是簡單的幾何形狀，可順利寫出元素的力平衡方程式並求得節點上之變位、應變及應力等
  - 藉由內插法求得元素內任意點的變位、應變及應力等



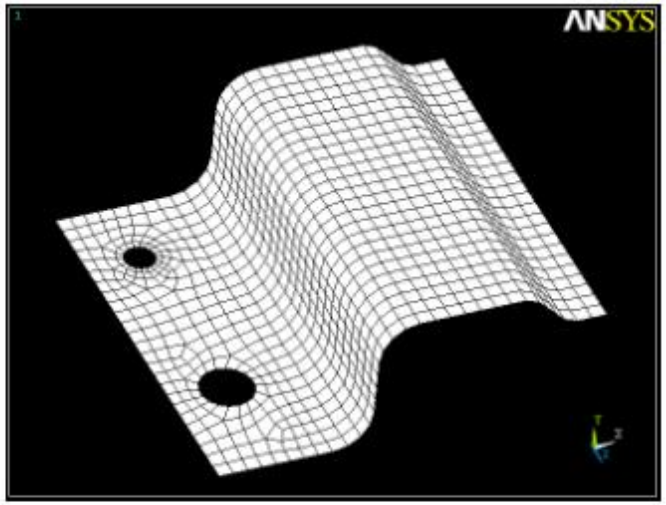
Computer Aided Engineering (CAE)

- **Pre-processing**
  - Geometry
  - Mesh (Element type)
  - Materials
  - Boundary and loading conditions
- **Solution**
- **Post-processing**
  - Present the results by graphs…

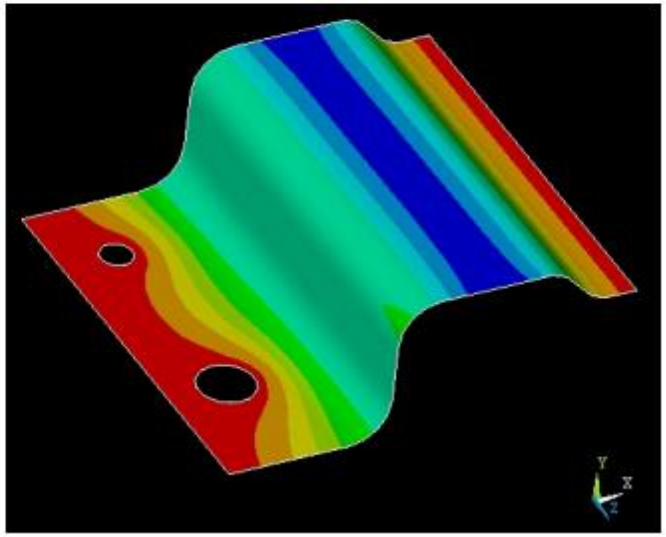




(a)實際工程問題



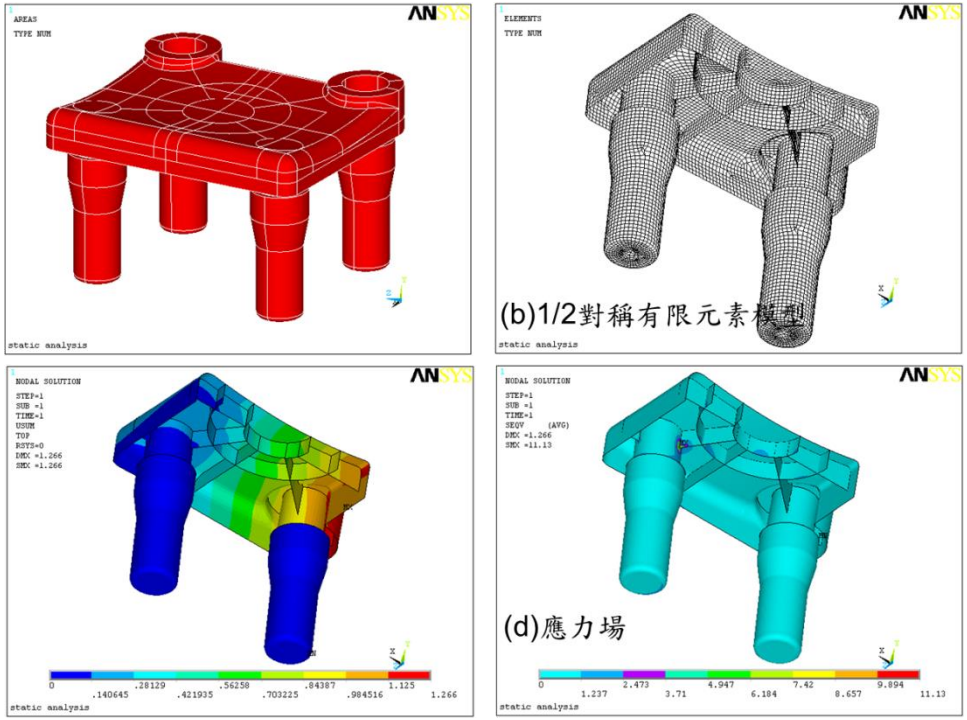
(b)元素網格



(c)模擬之變形

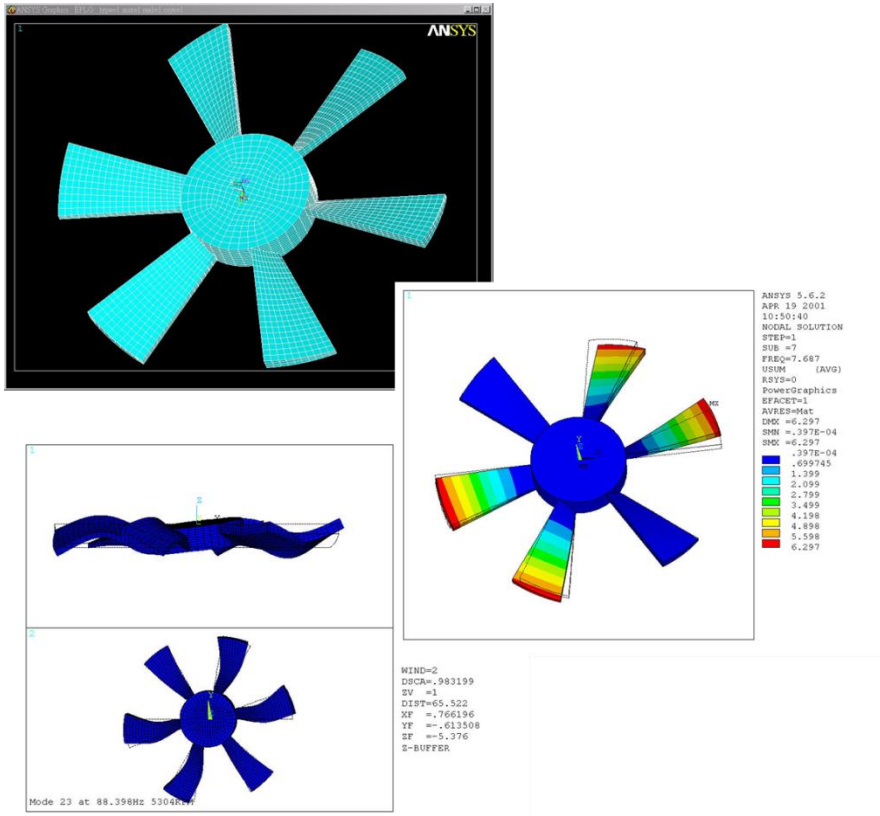
CAE general applications

❖電腦輔助工程 (Computer Aided Engineering, CAE)



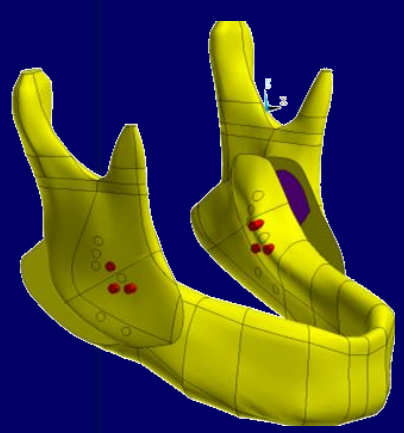
塑膠椅之力學分析

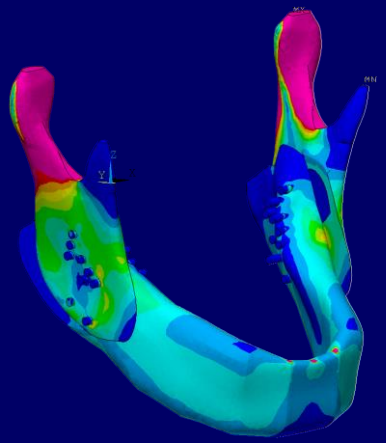
散熱風扇之模態分析

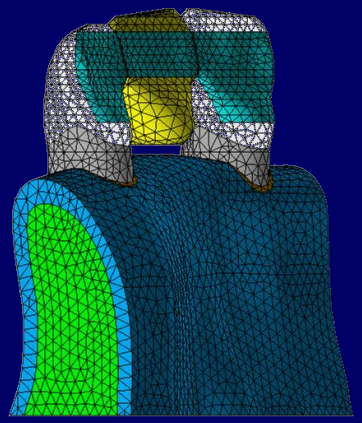


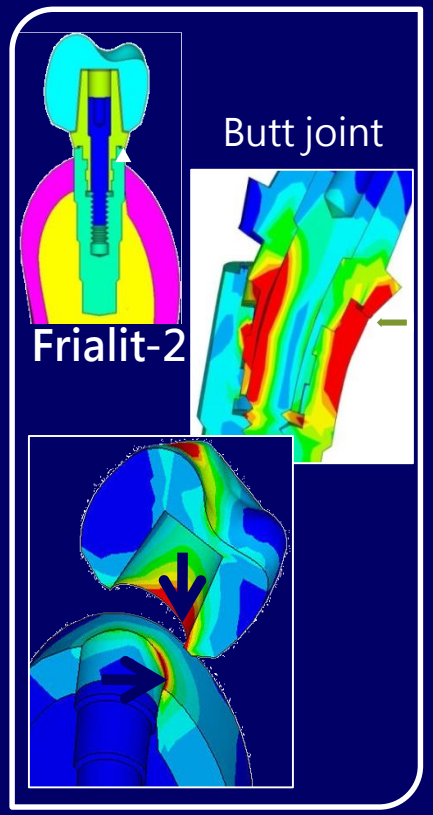
Computer aided engineering (CAE)

- **Computer Aided Engineering**
  - **CAE (Finite Element Method)**
- **Finite Element Method (FEM)**
  - **FEM is suitable theoretically for any structure**
    - **irregular geometry**
    - **inhomogeneity, anisotropy material properties**
    - **complex loading**
  - **Powerful analytical tool in biomechanics**

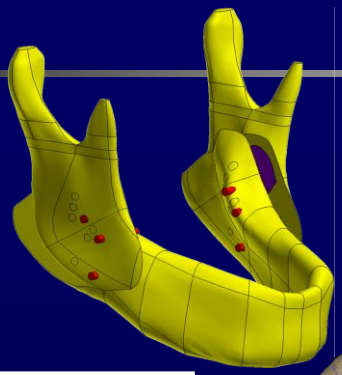


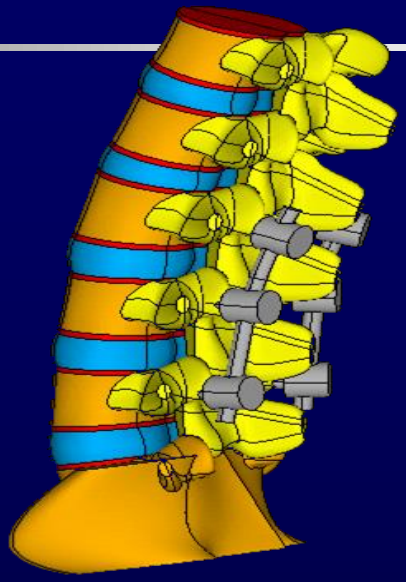


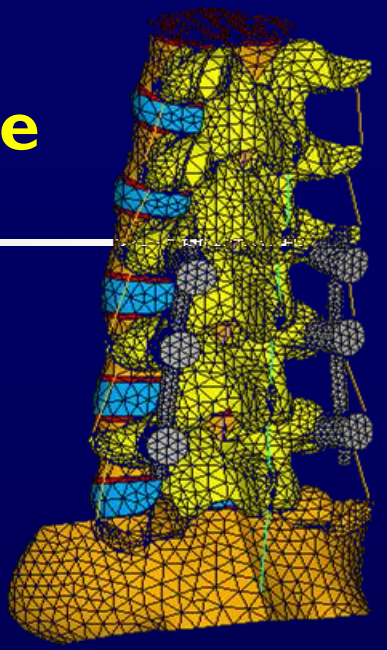


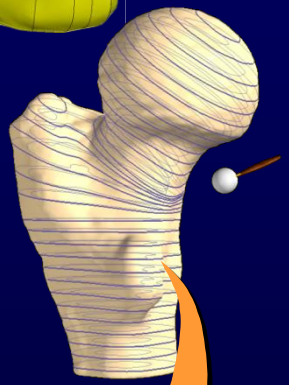


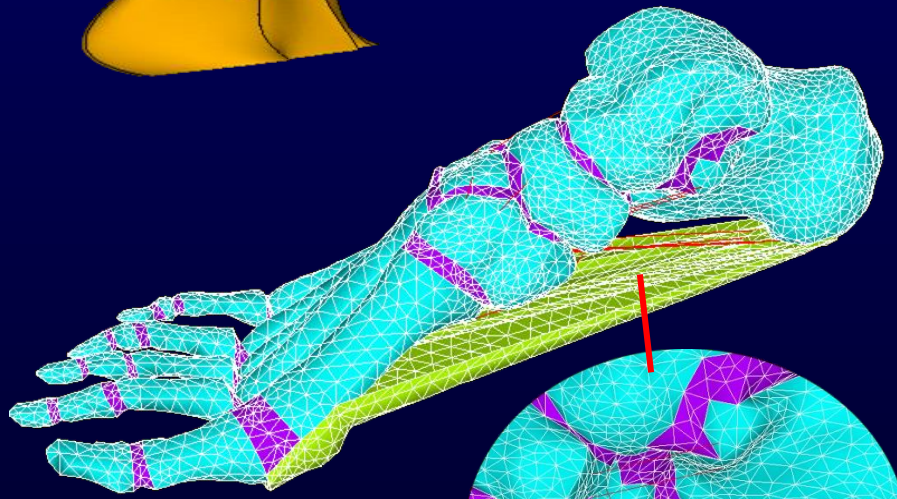
3D modeling for biological structure

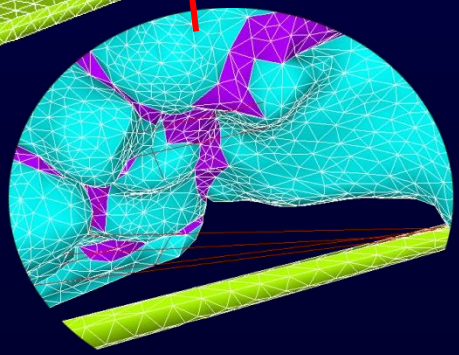


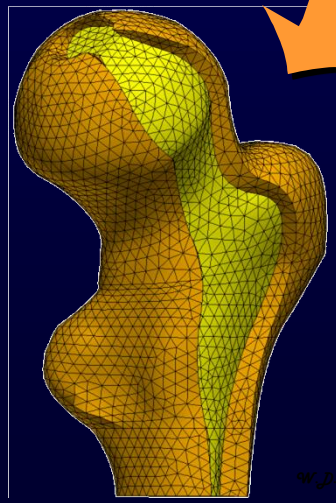








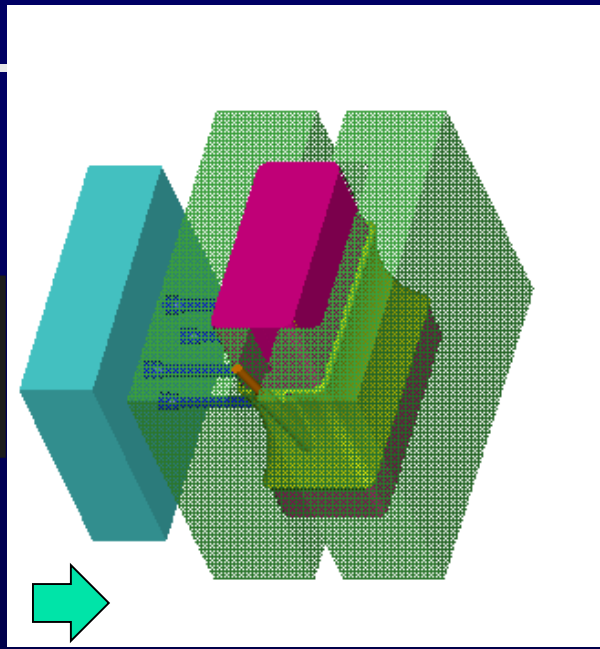


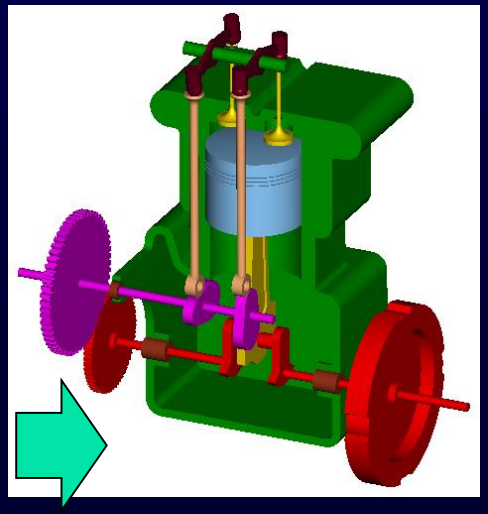


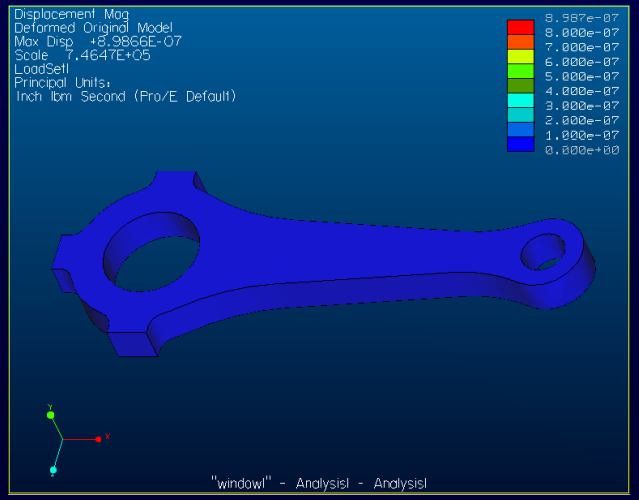
3C

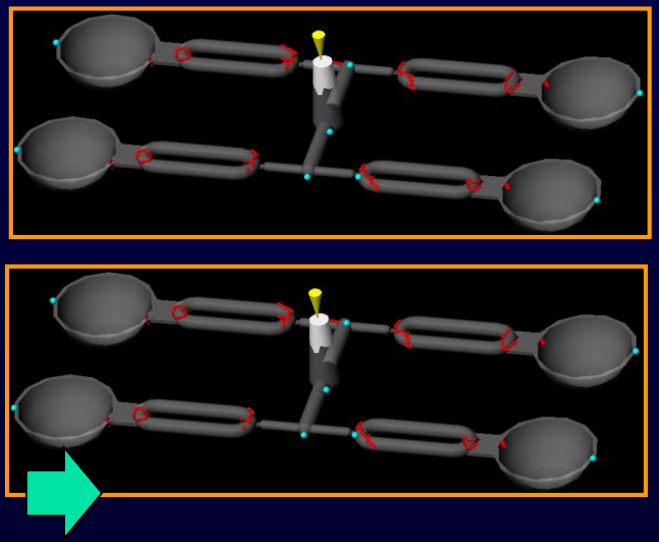
- **Forward Engineering**

CAD ⟷ CAE → CAM



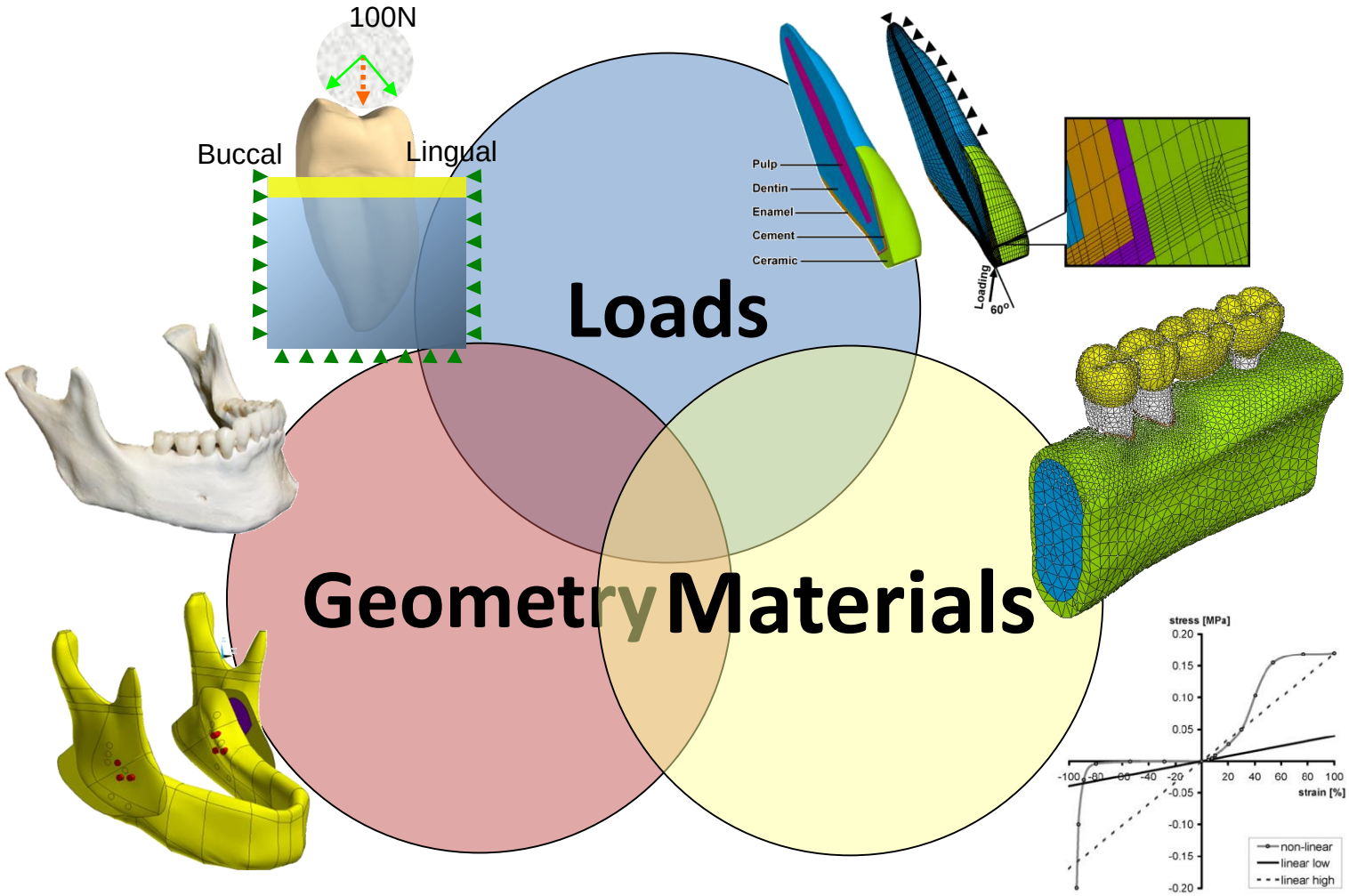




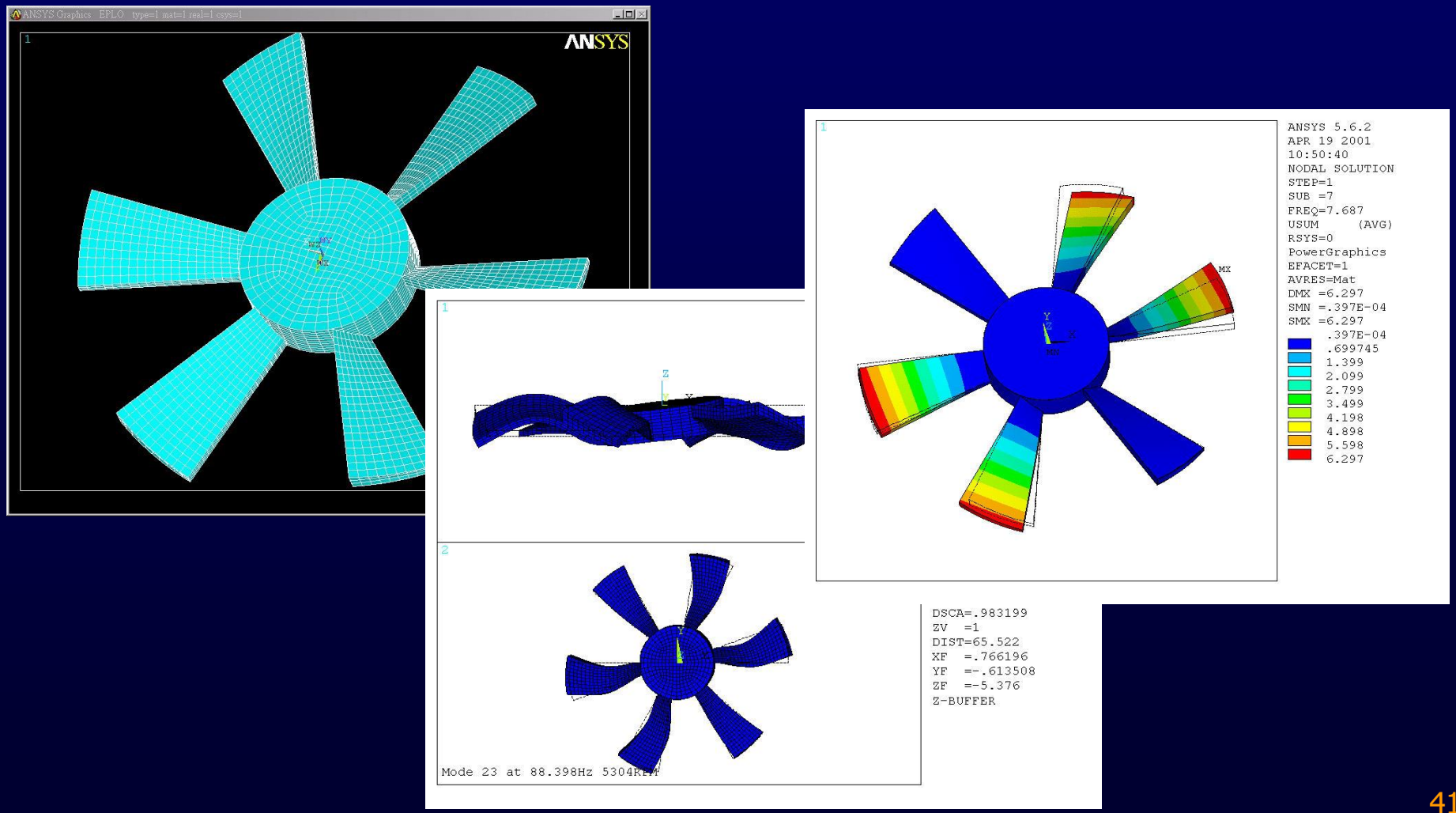


CAE key factors

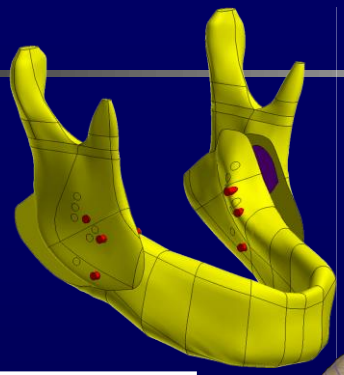
❖電腦輔助分析 (Computer Aided Engineering, CAE)

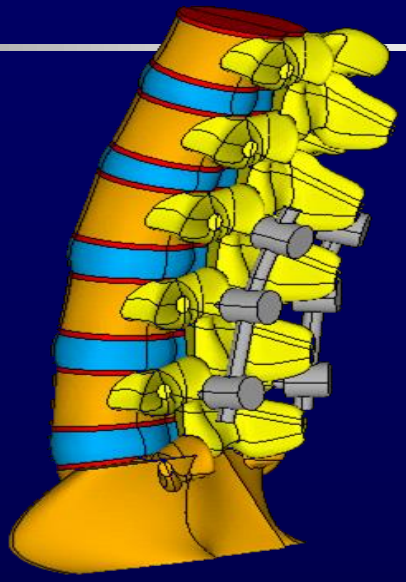


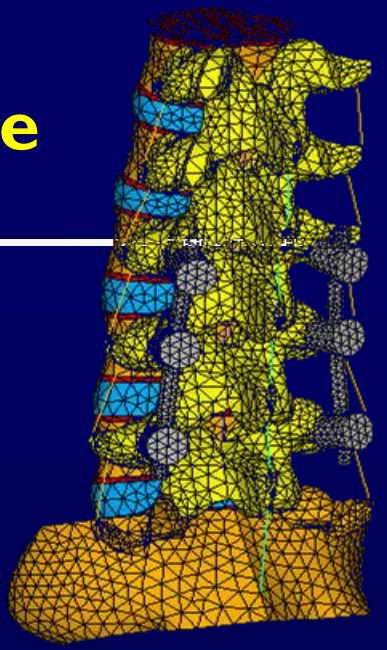
3D modeling for biological structure

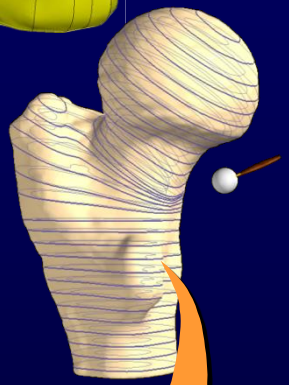


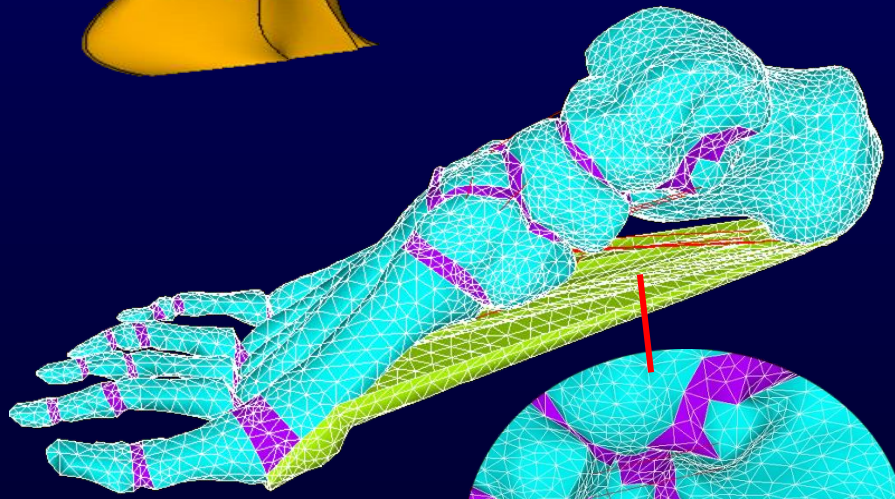
3D modeling for biological structure

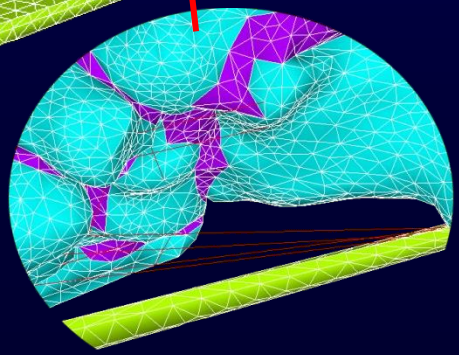


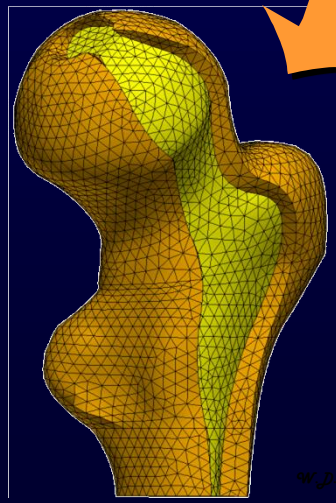




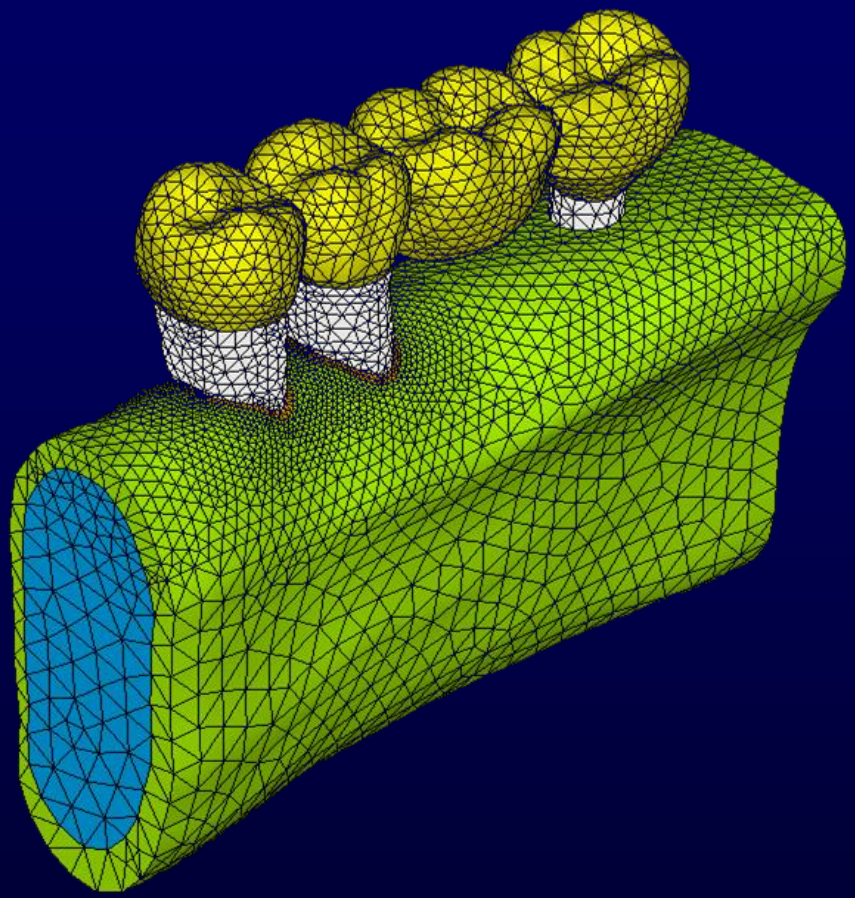








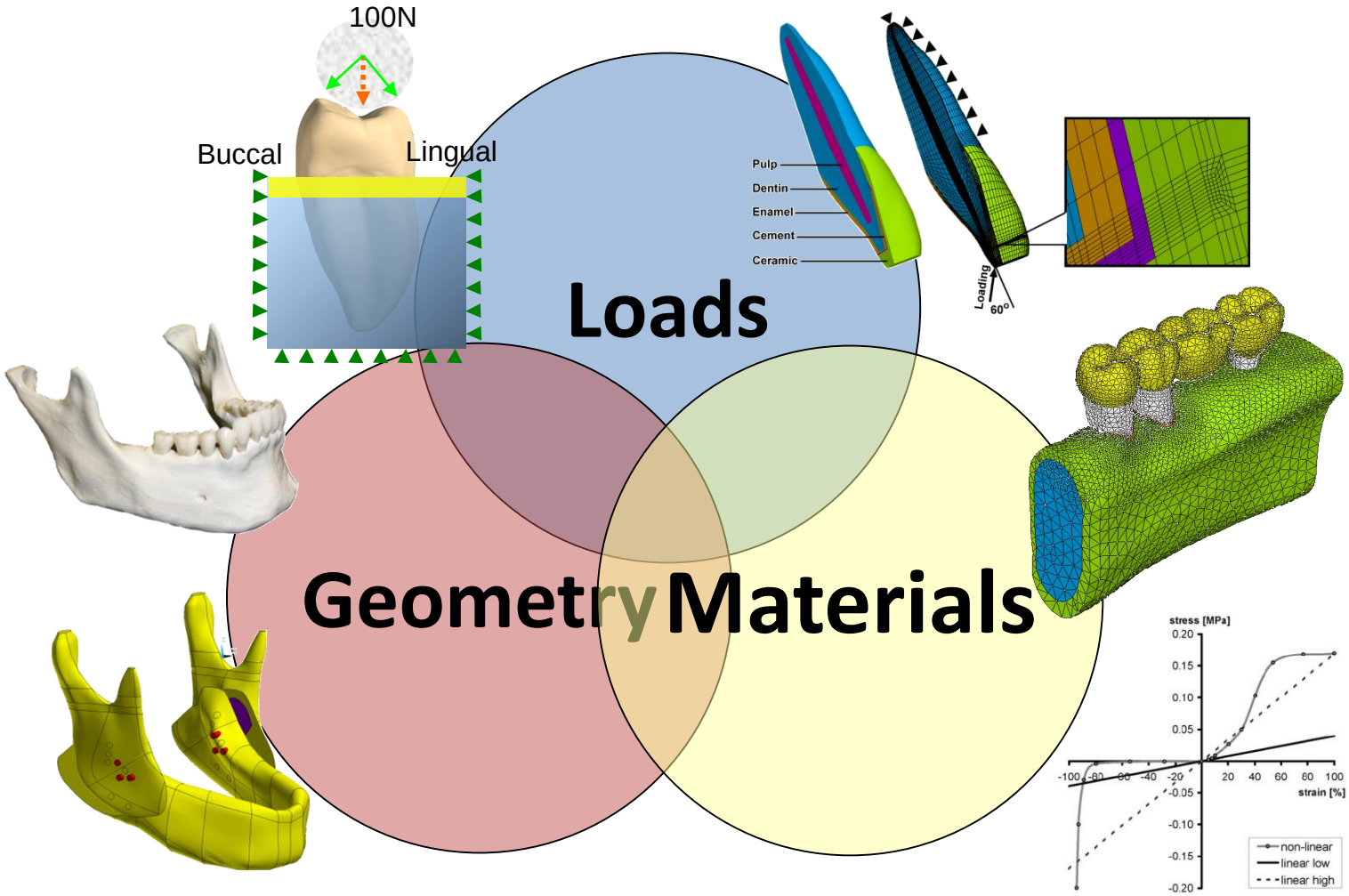
3D modeling for biological structure



C.L. Lin, J.C. Wang*, S.T. Chen, "Evaluation of stress induced of implant type and number of splinted teeth in different periodontal supported tooth-implant supported FPDs: a nonlinear finite element analysis", *Journal of Periodontology*, Vol. 81, pp.121-130, 2010.

CAE key factors

❖電腦輔助分析 (Computer Aided Engineering, CAE)



Non linear analysis

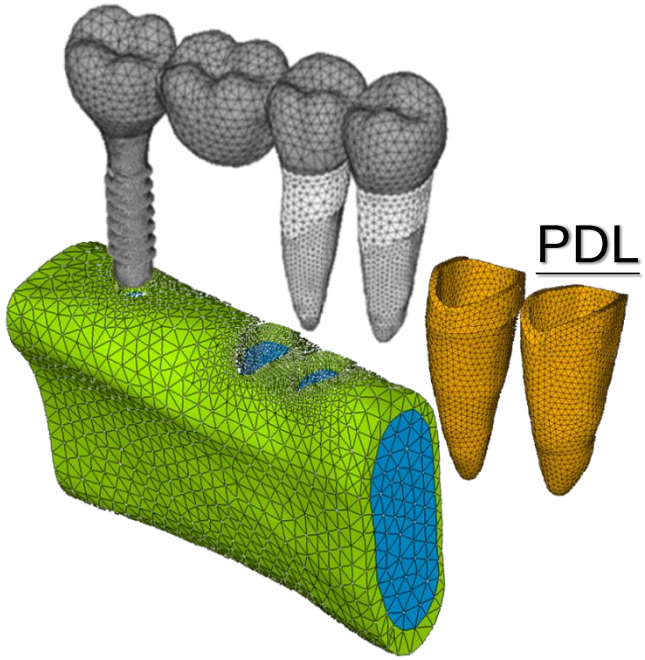
- **Material property**
  - **Non-homogeneous, anisotropic**
  - **Viscous-elastic, Hyperelastic (PDL)**
- **PDL**

Authors	Elastic modulus (MPa)	Poisson's ratio
Vollmer	0.05/0.22	0.3
Andersen	0.07/0.8-68.9/13.8	0.49/0.3-0.45/0.49
Yettram	0.18	0.49
Tanne	0.67	0.49
Williams	1.5/100	0-0.45
Korioth	2.5-3.2	0.45
Farah	6.9	0.45
Takahashi	9.8	0.45
Ree	50	0.49
Cook	68.9	0.49
Ko	68.9	0.45
Atmaram	171.6	0.45
Thresher	1379	0.45
Goel	1750	0.49

CAE-material

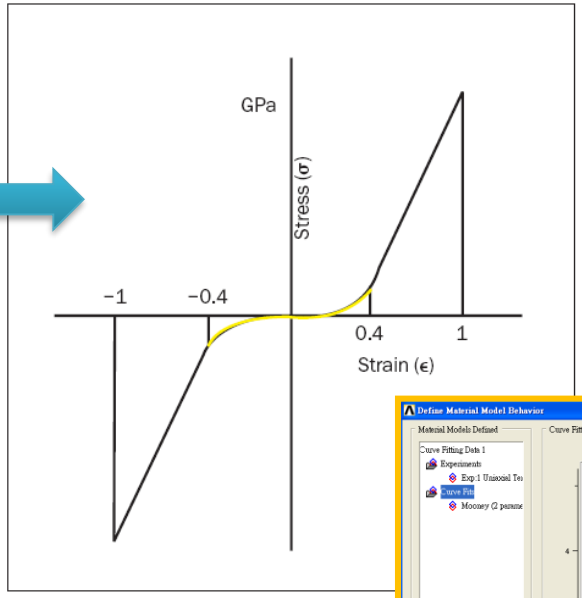
❖電腦輔助分析 (Computer Aided Engineering, CAE)

Materials

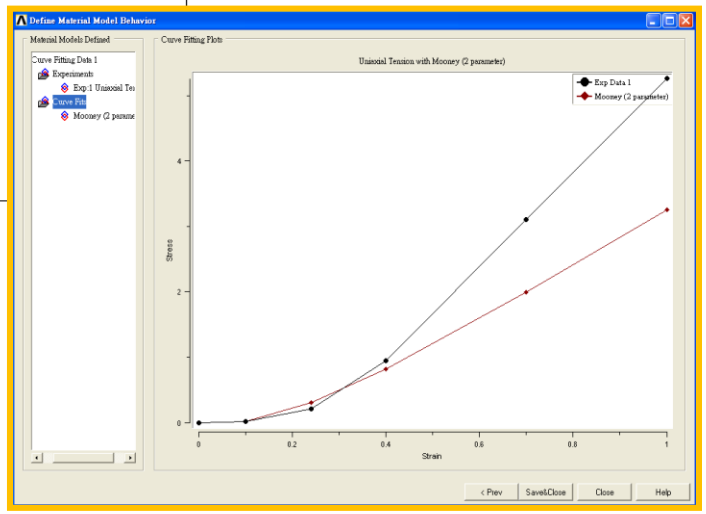


PDL

Nonlinear material property



$$\sigma = 1.498246 \times 10^{-2}\,\epsilon^{3}$$

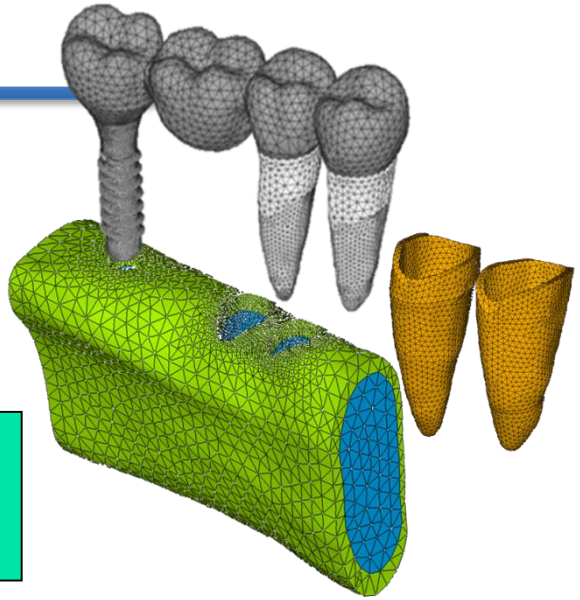


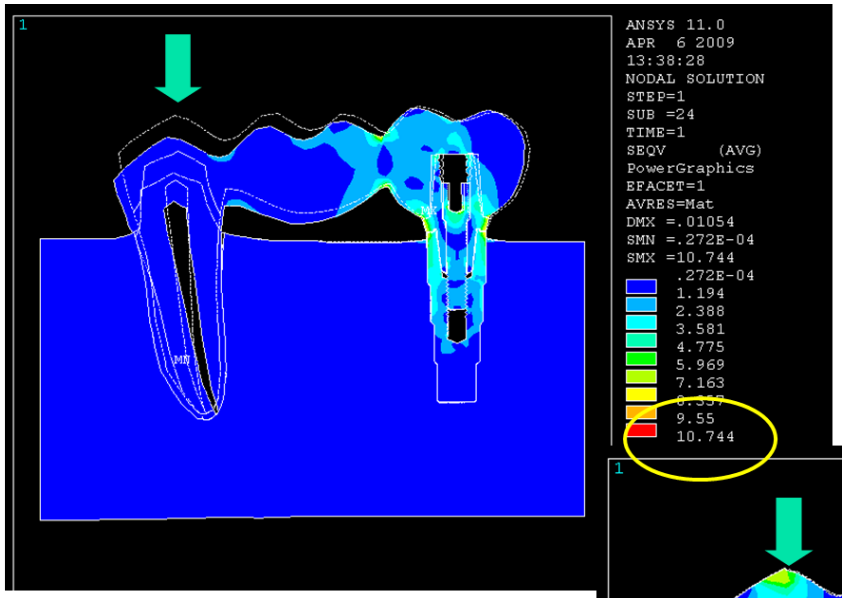
Material property simulation

CAE-material

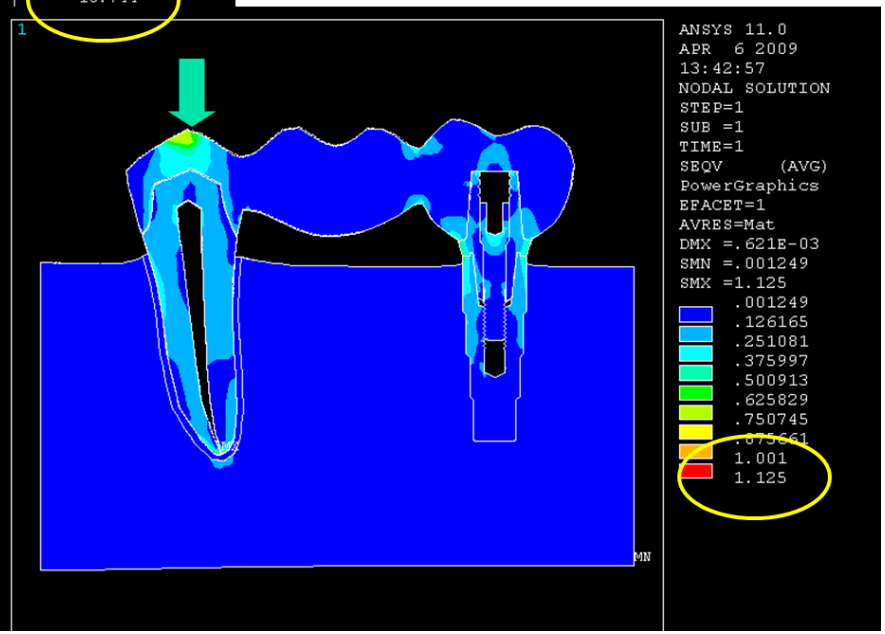
❖電腦輔助分析 (Computer Aided Engineering, CAE)

Materials





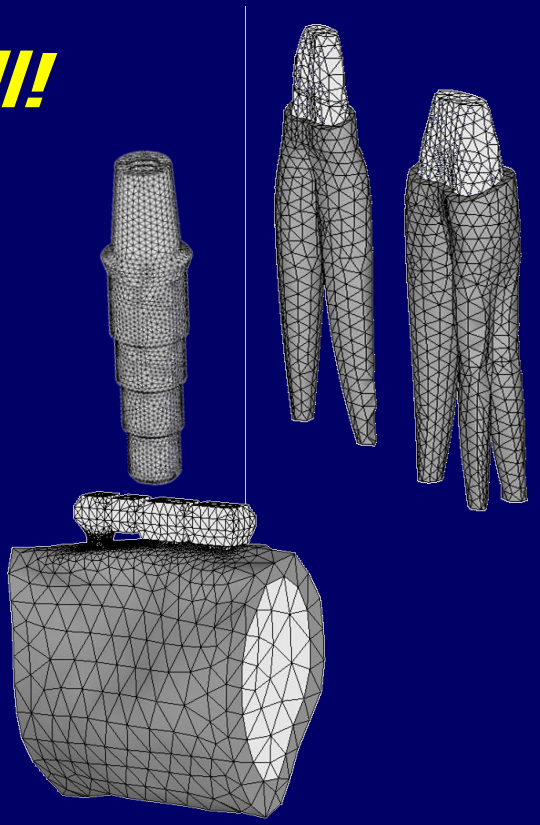
Hyper Max Dis = -10.31
Normal Max Dis = -1.23



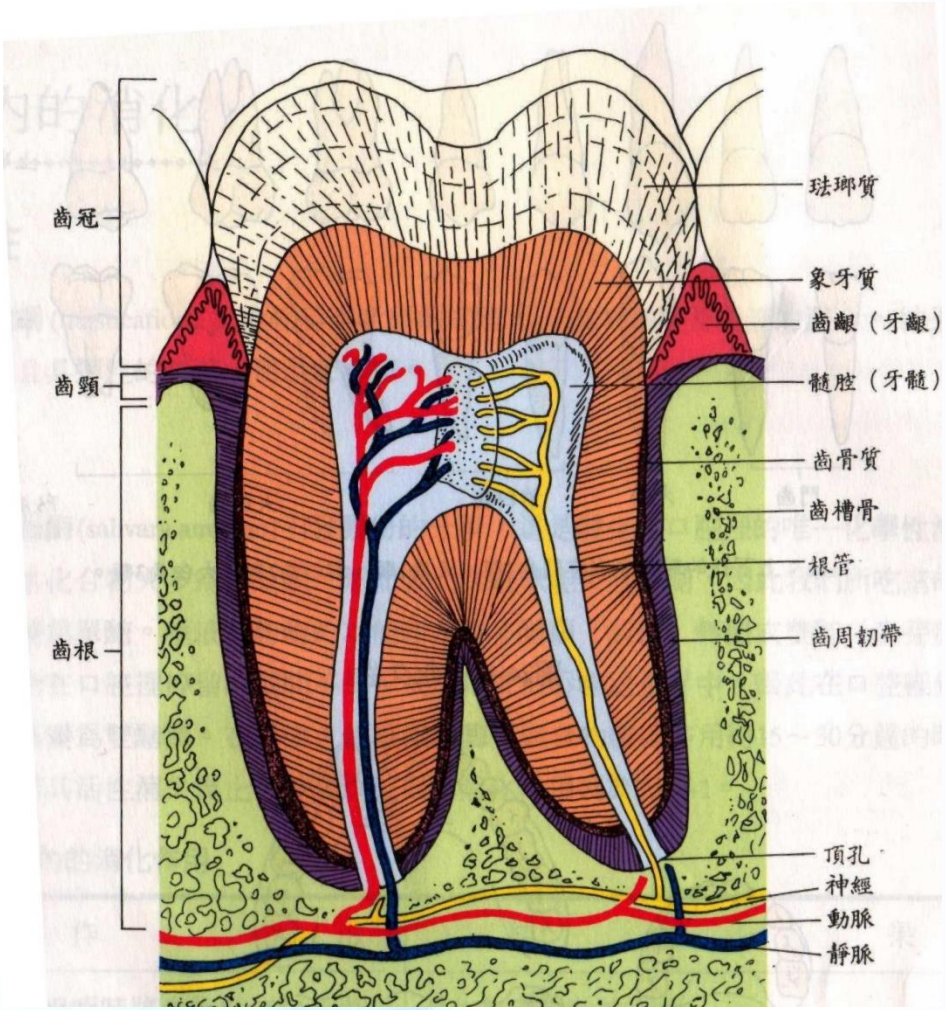
Displacement 及 stress
均有極大差異

Easy to do, hard to do well!

Validation with experiments



自然牙齒構造



自然牙齒

- 第一套乳牙- 20顆
- 第二套恆牙- 32顆

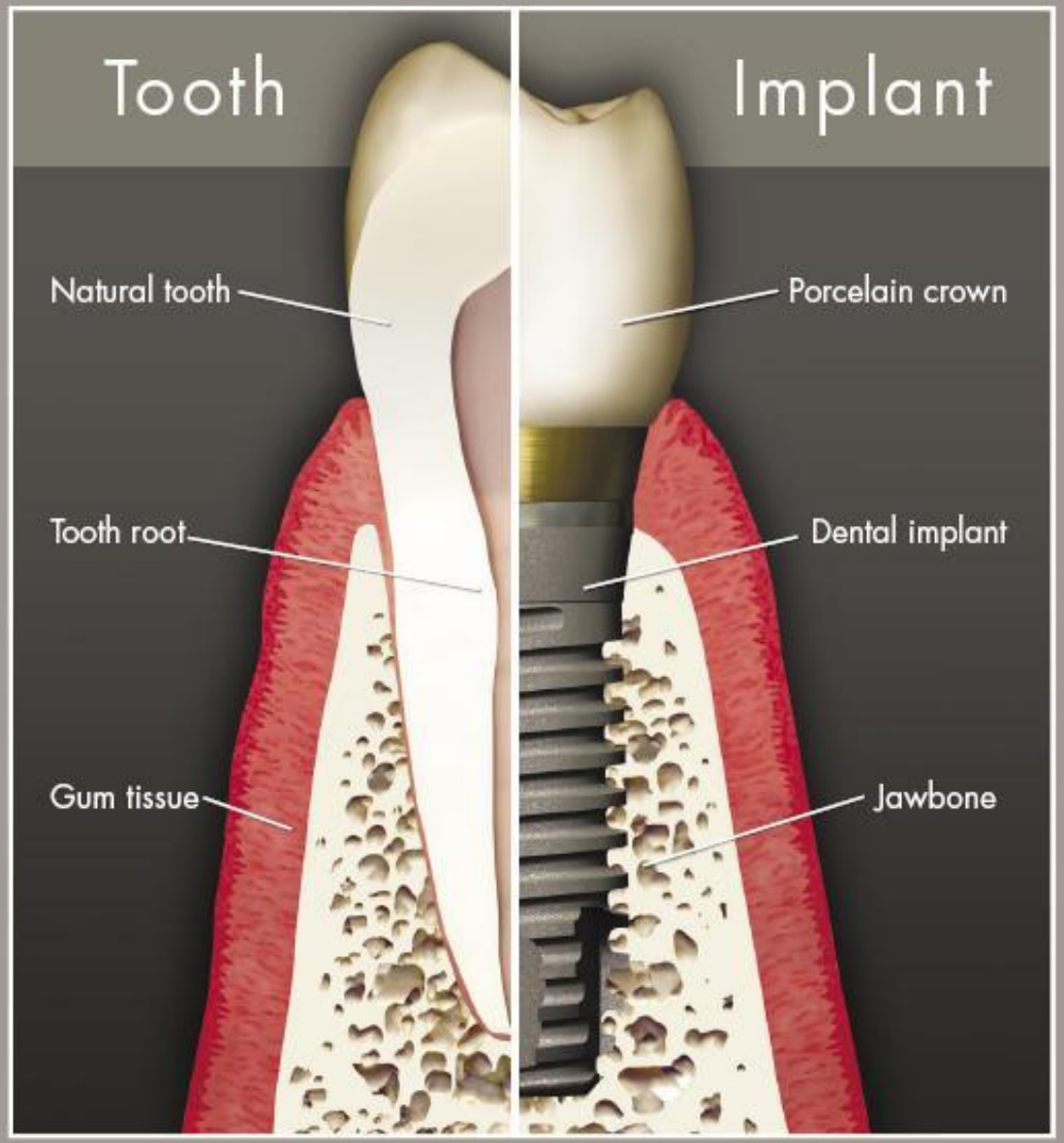
齒槽骨

- 由膠質、礦物質、纖維蛋白和基質所組成。
- 牙齒脫落會發生骨吸收現象

何謂人工牙根?

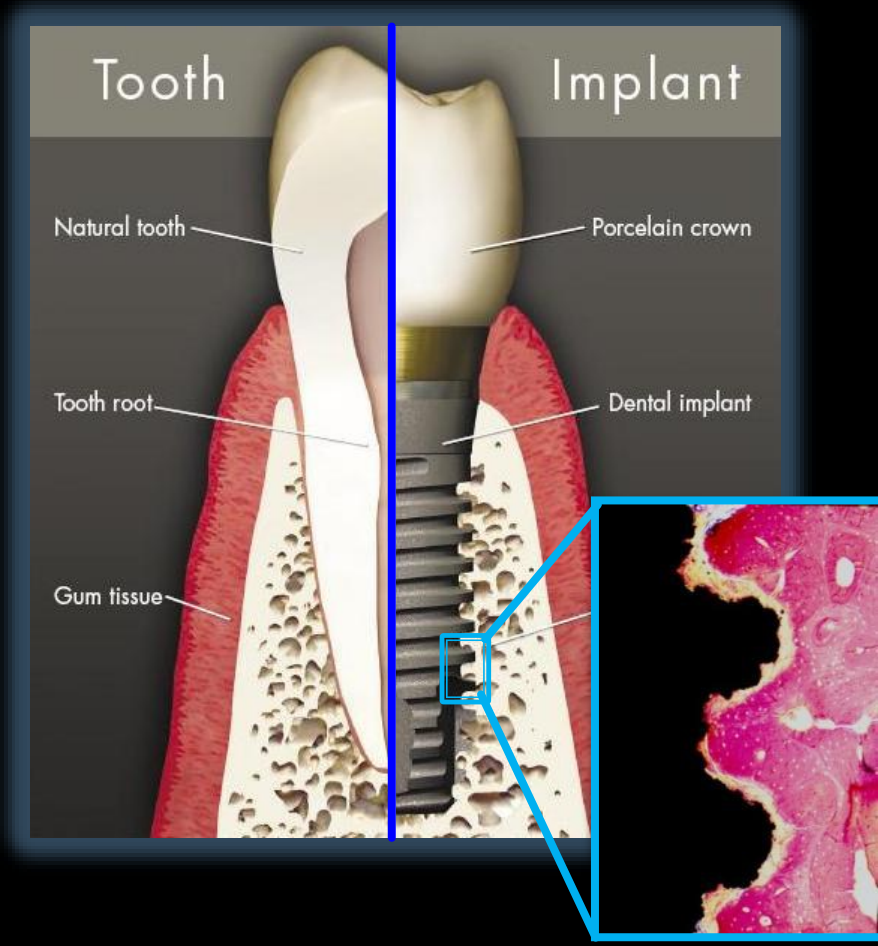
- 以純鈦金屬或鈦合金人工牙根種植到缺牙區的齒槽骨
- 人工牙根與骨細胞產生緊密的結合(骨整合)
- 在人工牙根表面必須經過特殊的處理

Tooth Replacement with Dental Implants



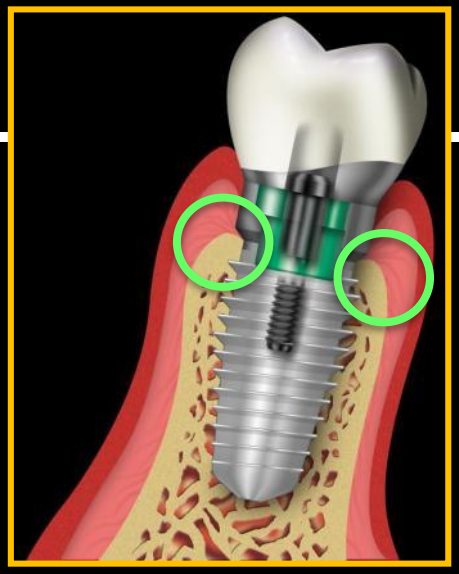
人工牙根簡要

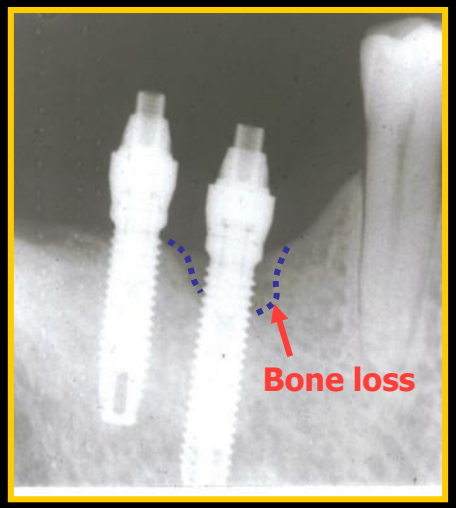
- 人工牙根
  - 定義
    - 以人工替代物種植到缺牙區的齒槽骨以取代原本牙齒的功能
  - 目的
    - 恢復口腔中牙齒咀嚼之功能
  - 骨整合機制
    - 必須經過3至6個月人工牙根的表面與骨細胞產生緊密的結合



人工牙根成功條件

- 人工牙根成功條件
  - 初期：良好的骨整合效果
  - 長期：避免骨整合流失
- 影響骨頭受力之因素
  - 生物力學因素
    - 人工牙根及支台外形設計
    - 人工牙根植入形式
    - 咬合力形式

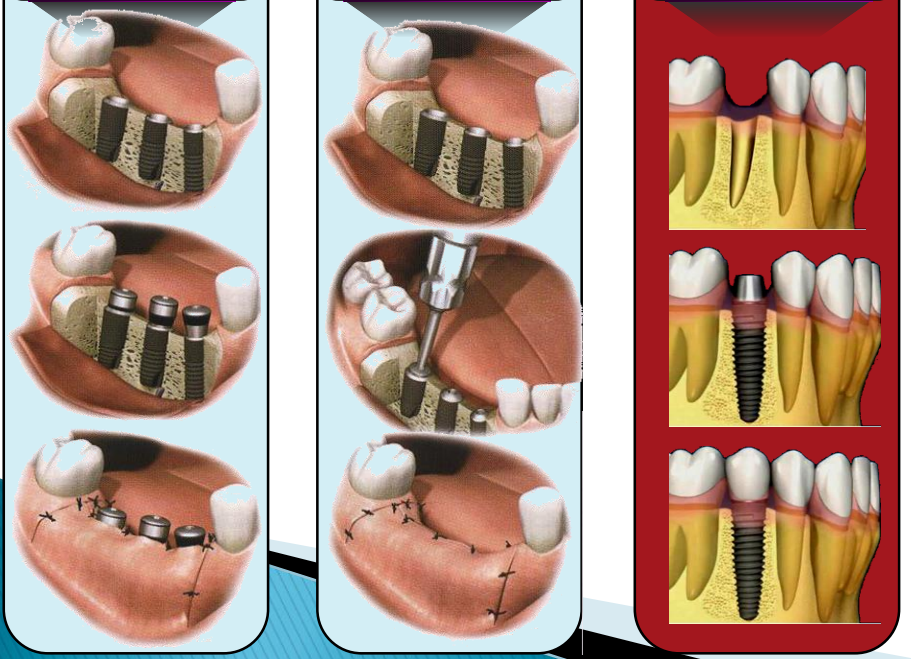




Dental Implant

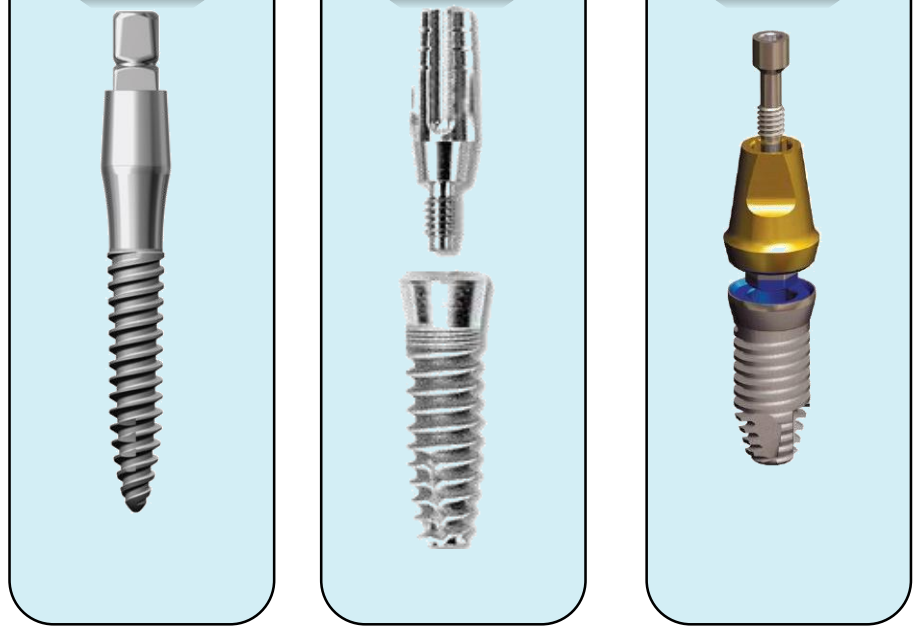
Surgical classification

- 1 stage
- 2 stage
- Immediate placement



Feature classification

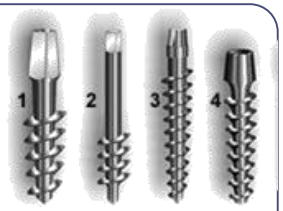
- 1 piece
- 2 piece
- 3 piece



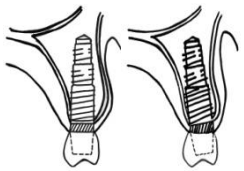
Success rate & factors

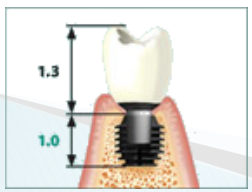
Immediate placement 80%
Traditional placement 95%

Initial stability



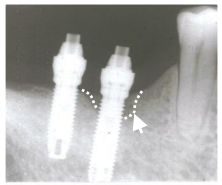
Implant design

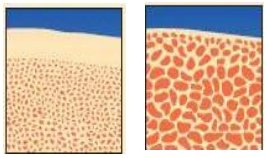

Placement direction



Crown to implant ratio

Bone situation


Bone resorption


Bone density


Bone height

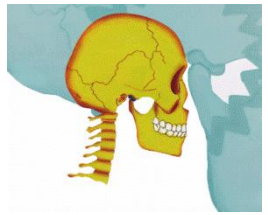
Clinical factor


Bone loss after tooth extract


Bad anatomy location


Infection

Patient habits


Grinding


Smoke


Diabetes

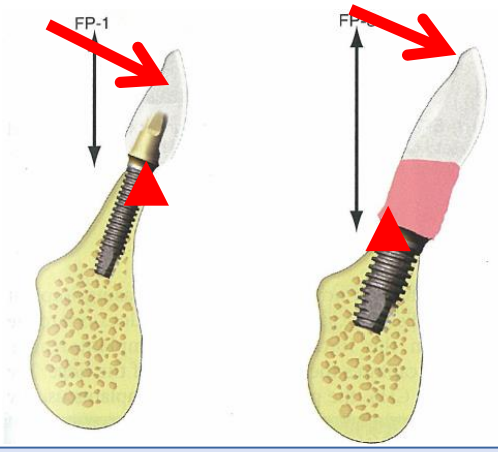
Biomechanical factors

Initial stability

- Implant design
- Placement direction
- Crown high space

Bone situation

- Bone resorption
- Bone density
- Bone height



CHS 會產生“槓桿” 現象
越高的CHS會產生越大的應力

CHS: Crown Height Space冠高空間

- **生物力學&生理機械**
  Biomechanics & Mechano biology
  - 人工牙根設計
  - 骨質流失
  - 骨質密度
- **病患生理&醫師考量**
  - 植體植入位置
  - CHS
  - 牙周狀態/骨質密度

生物力學&生理機械-人工牙根設計綱要

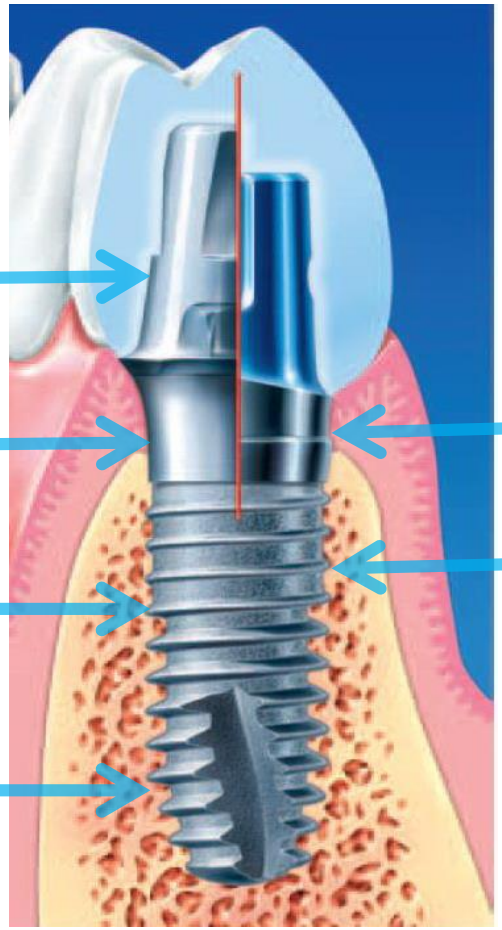
巨觀考量

連結器 (Connection)

頸部設計 (Crest design)

主體螺牙 (Body thread)

植體外型 (Implant shape)



微觀考量

近端螺紋 (Proximal thread)

表面處理 (Surface treatment)

人工牙根設計 (1/2)

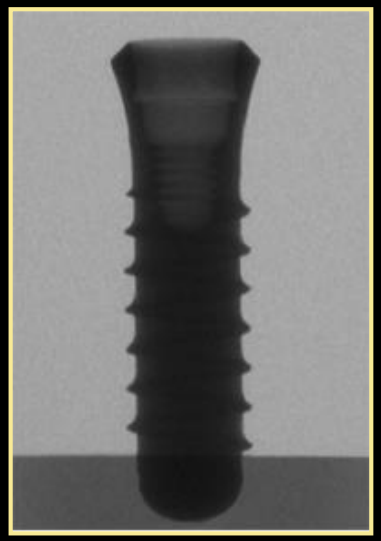
	Nobel Biocare	Straumann (ITI)	Innovations (3i)	Densply (Frialit-2)	Astra Tech (Astra)
植體圖					
植體外型	斜錐狀	圓柱狀	斜錐狀	階梯狀	斜錐狀
主體螺牙	深螺紋 自攻設計	淺螺紋	深螺紋 自攻設計	無	深螺紋 自攻設計
頸部設計	無	無	Platform switching	無	Platform switching

人工牙根設計 (2/2)

	Nobel Biocare	Straumann (ITI)	Innovations (3i)	Densply (Frialit-2)	Astra Tech (Astra)
植體圖					
連結器設計	三瓣式搭配螺絲	Morse taper	內六角搭配螺絲	內六角搭配螺絲	內十二角搭配螺絲
近端細螺紋	有	無	無	無	有

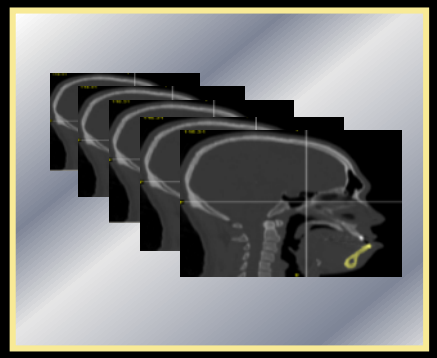
醫學影像掃描及處理

- 醫學影像掃描
  - 上/下顎骨
    - 健康40歲男性
    - 小臼齒區無牙狀態
    - CT掃描間隔：1mm
  - 人工牙根
    - 廠牌：
      - Nobel Biocare (Replace)
      - Straumann (ITI)
      - Biomet (3i)
      - Densply (Frialit-2, XiVE)
      - Astra Tech (Astra)

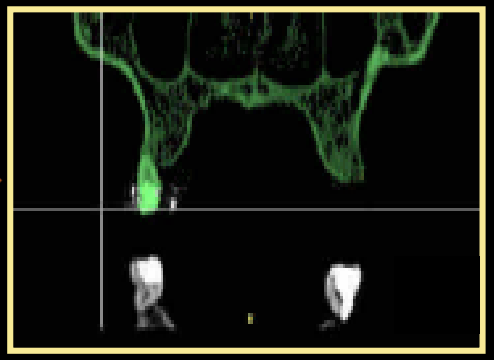


醫學影像掃描及處理

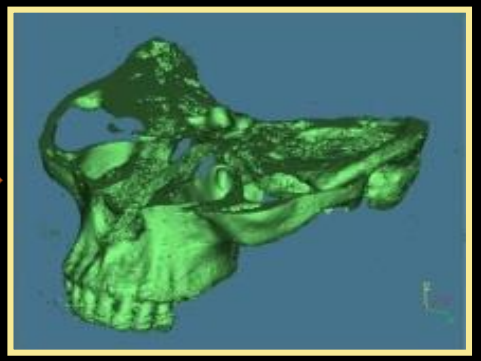
- 上顎骨醫學影像掃描及處理



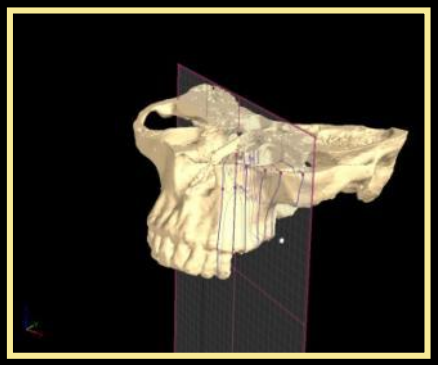
醫學影像處理



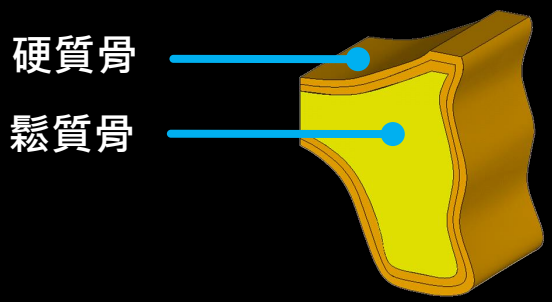
閥值調整及部位選取



影像重組



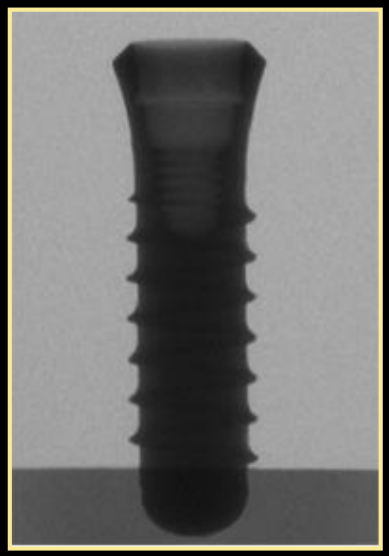
輪廓外形擷取



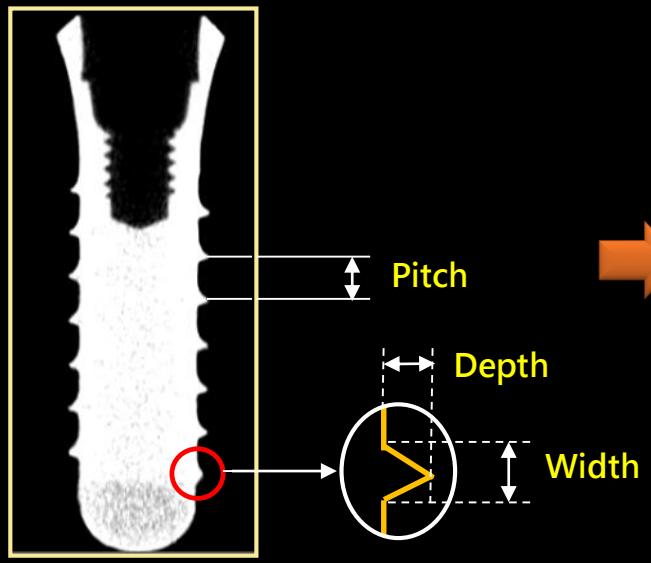
上顎第二小臼齒區
顎骨外型建構

電腦輔助工程設計(CAD)

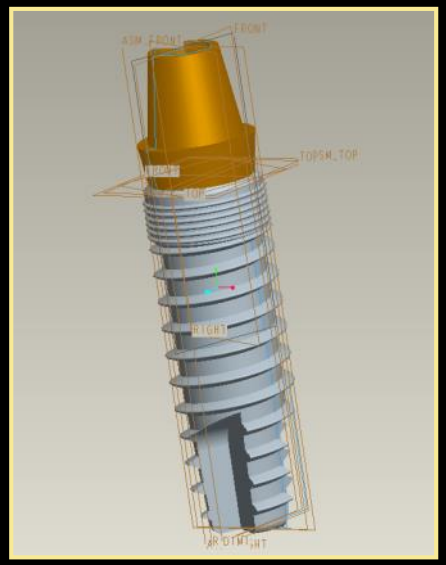
- 五大廠牌植體模型建構



醫學影像處理

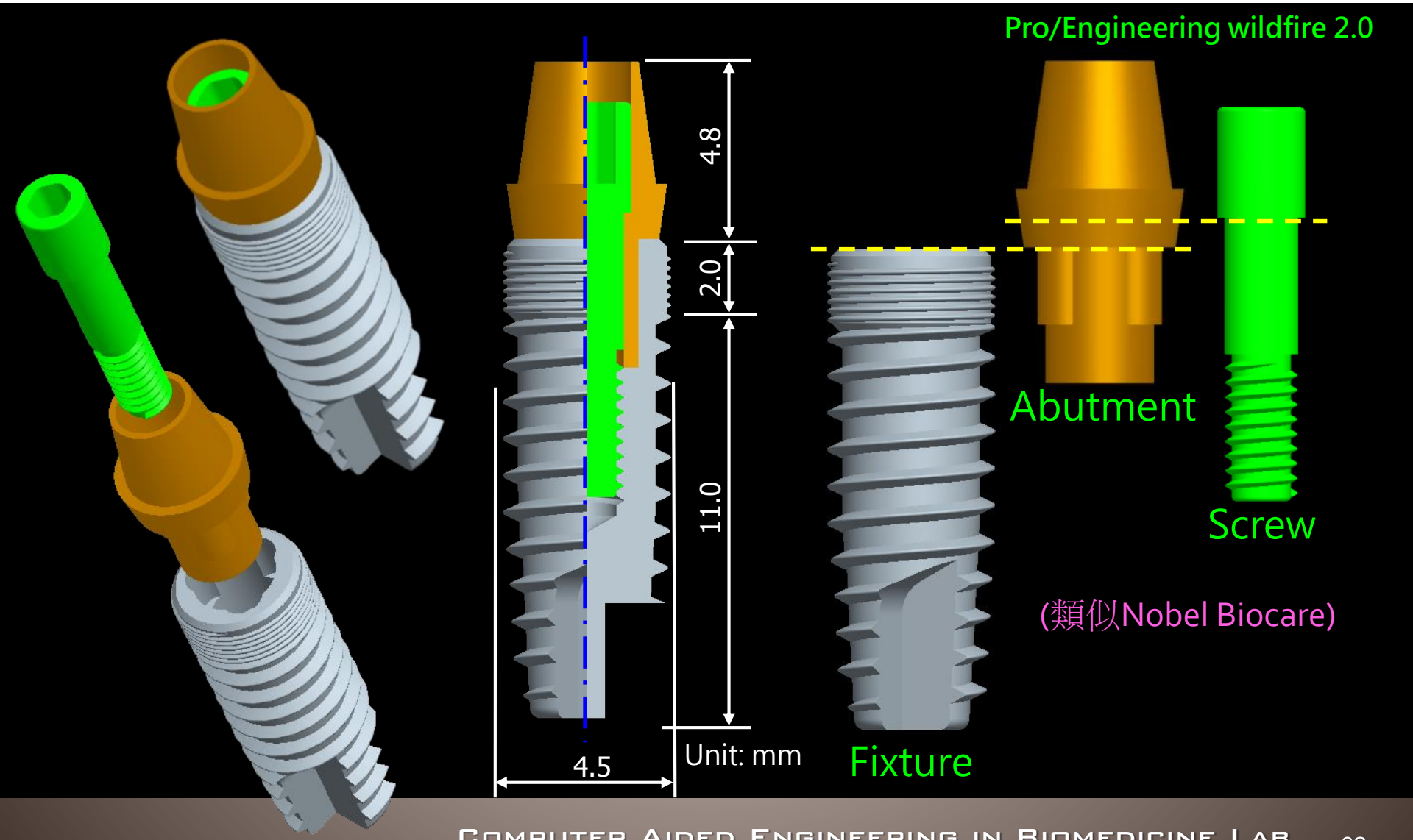


各部位尺寸量測



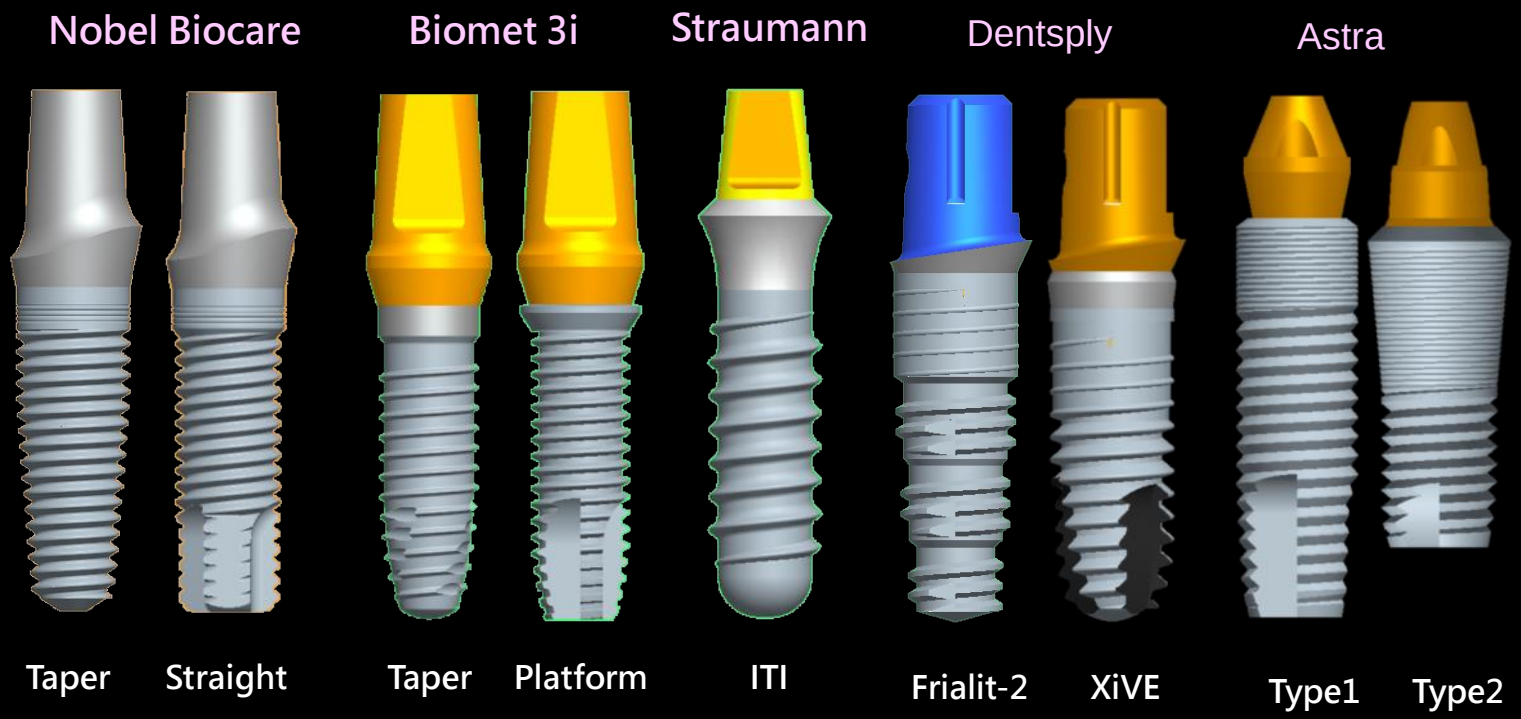
電腦輔助設計 (CAD)

設計 (三瓣搭配螺絲)


Pro/Engineering wildfire 2.0
4.8
2.0
11.0
4.5
Unit: mm
Fixture
Abutment
Screw
(類似Nobel Biocare)

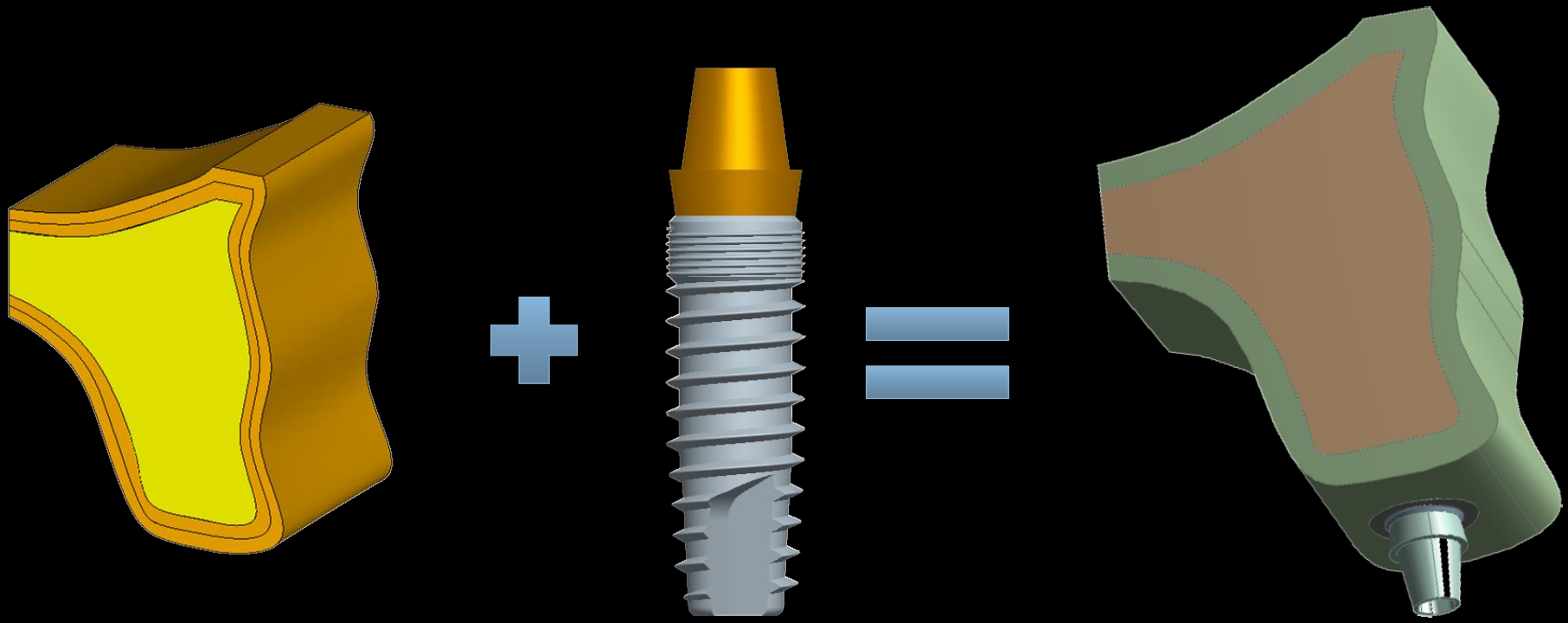
電腦輔助工程設計(CAD)

- 人工植體模型



有限元素模型建構

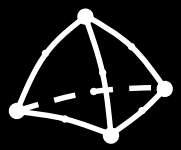
- 上顎骨與人工牙根模型組合
  - 各部位模型位置確立及布林運算



上顎骨模型　　人工植體模型　　顎骨/人工植體模型

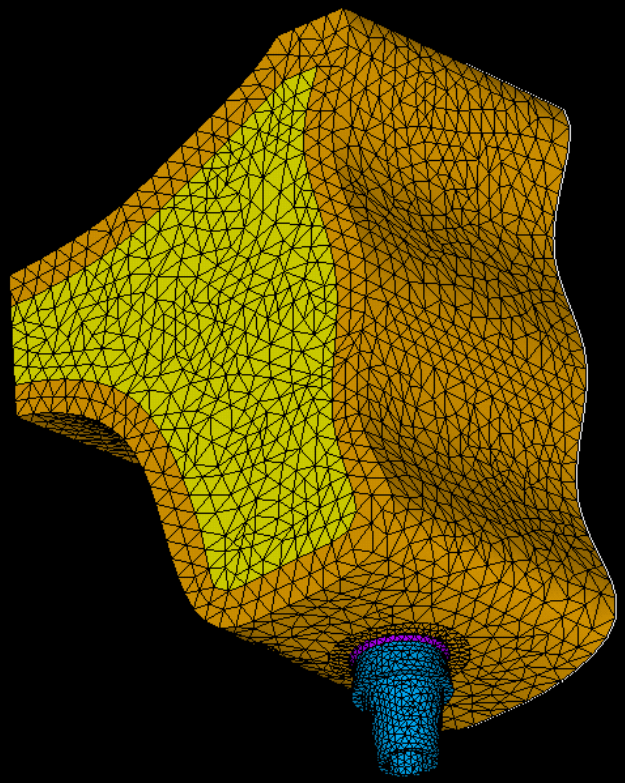
有限元素非線性模擬分析

- 模型網格化
  - 使用三維四面體十節點元素(Solid 92)進行自由化網格



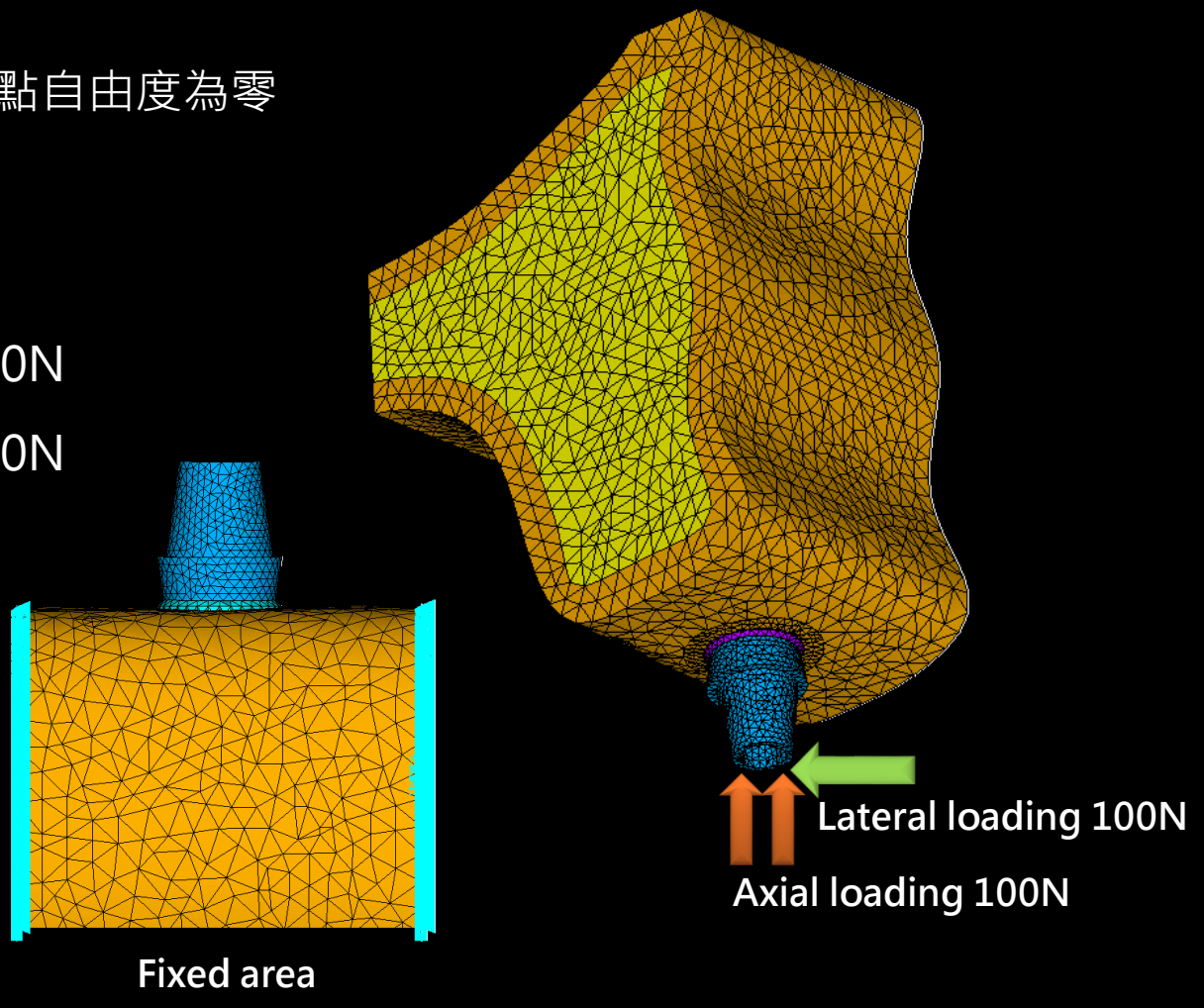
- 材料特性給定
  - 硬質骨、鬆質骨及植體皆為等向均質材料

	彈性係數 (MPa)	樸松比
硬質骨	14700	0.3
鬆質骨	1470	0.3
鈦合金	110000	0.35

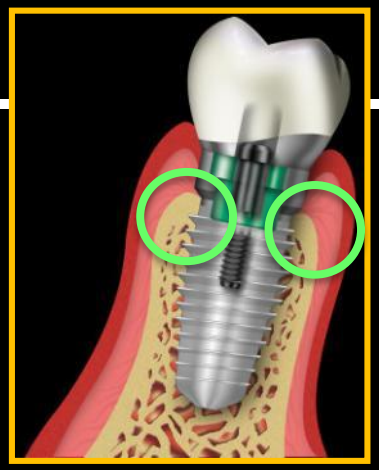


有限元素非線性模擬分析

- 邊界條件給定
  - 近遠心端處節點自由度為零
- 負載條件給定
  - 軸向負載：100N
  - 側向負載：100N



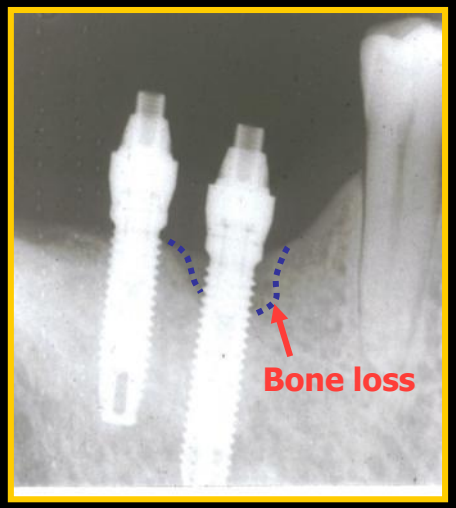
模擬分析觀察數值



- 人工牙根成功條件
  - 避免骨整合流失
  - 避免植體元件斷裂

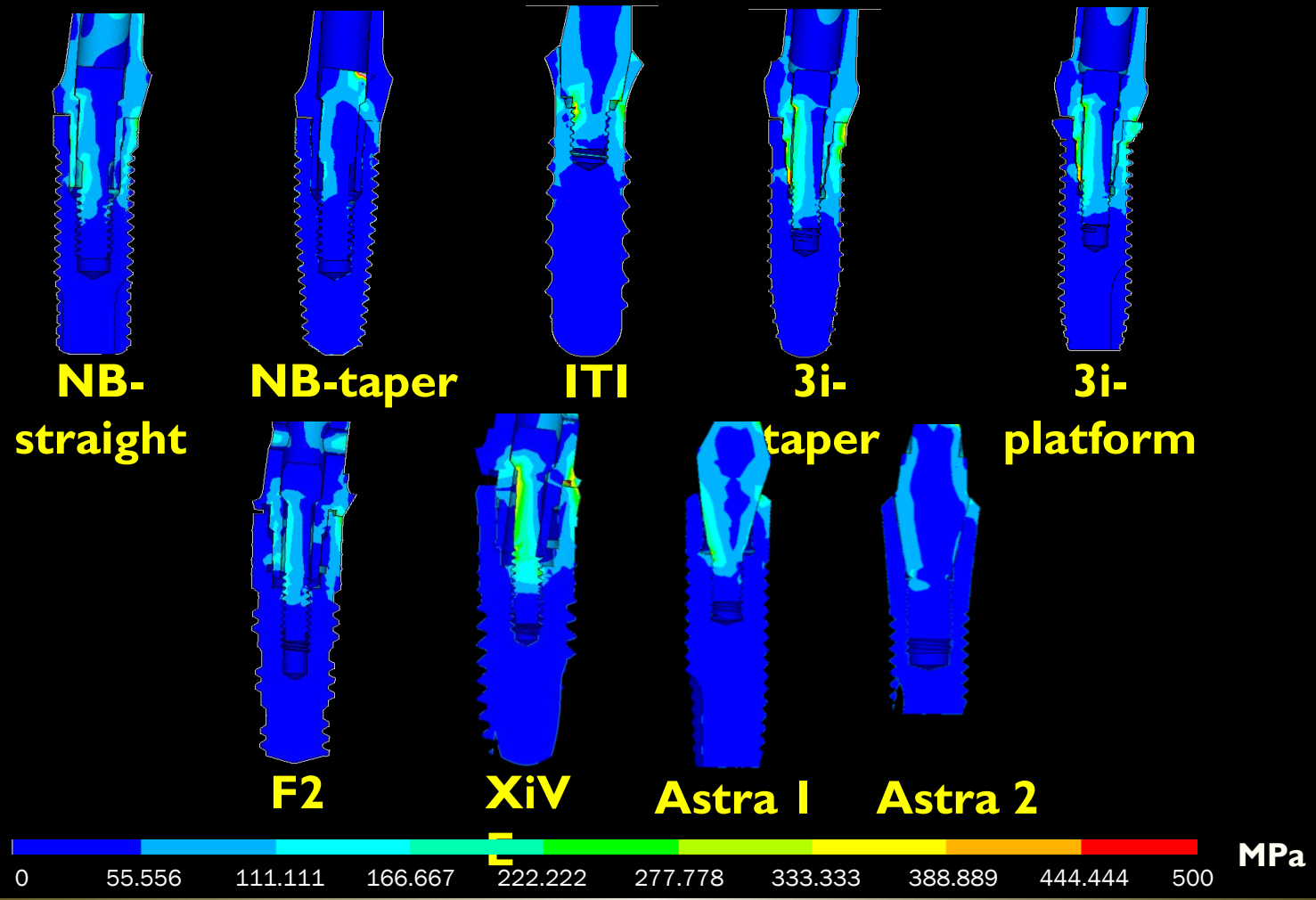
- 觀察結果
  - 骨頭應變值
    - 骨頭應變值(ustrain)超過4000時

      Frost. et. 2004
  - 人工植體應力值
    - 鈦金屬之破壞強度為 1000 MPa

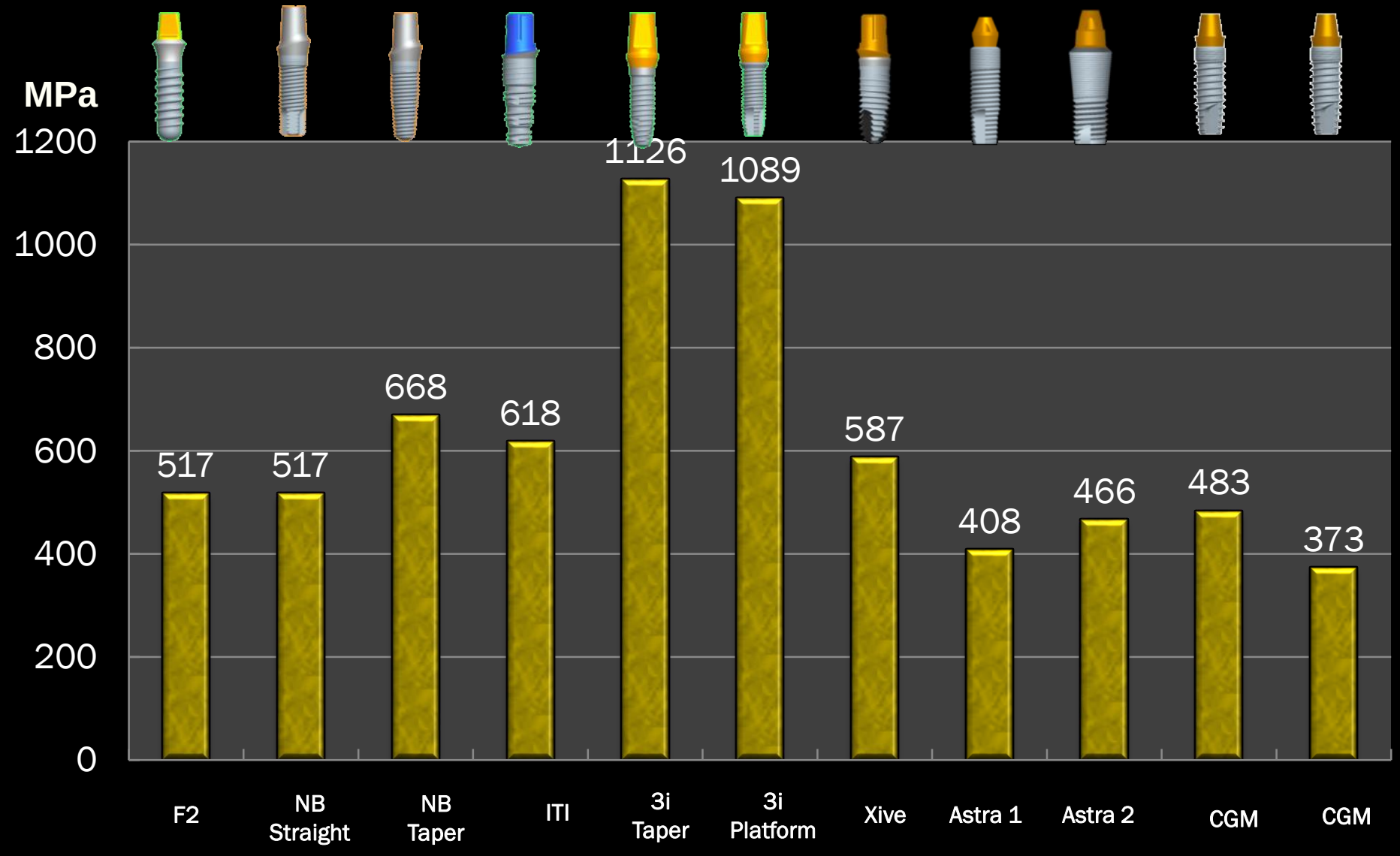


有限元素模擬分析結果(上顎)

- 植體應力分佈圖-側向負載



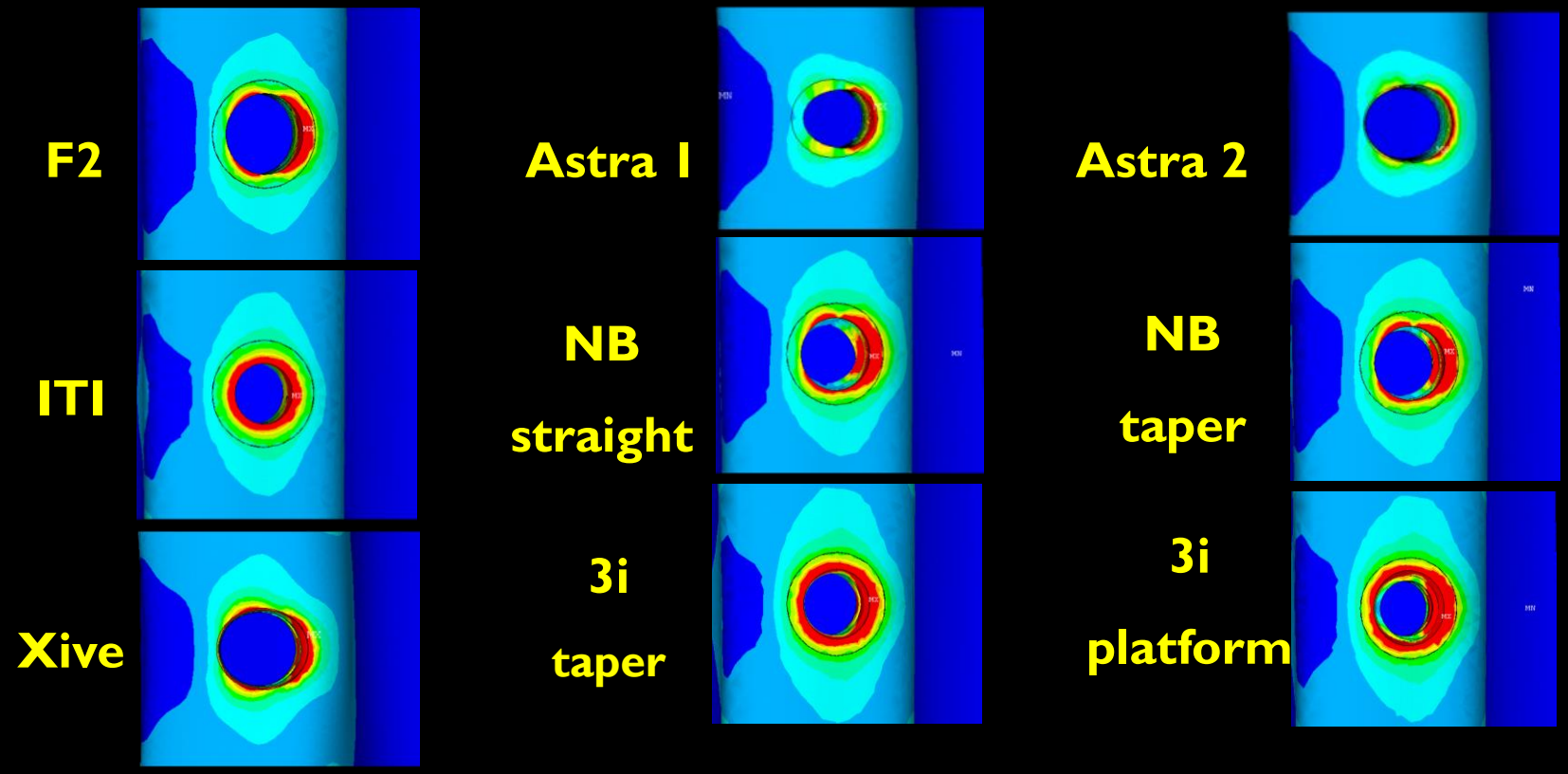
有限元素模擬分析結果-側向負載之植體應力值



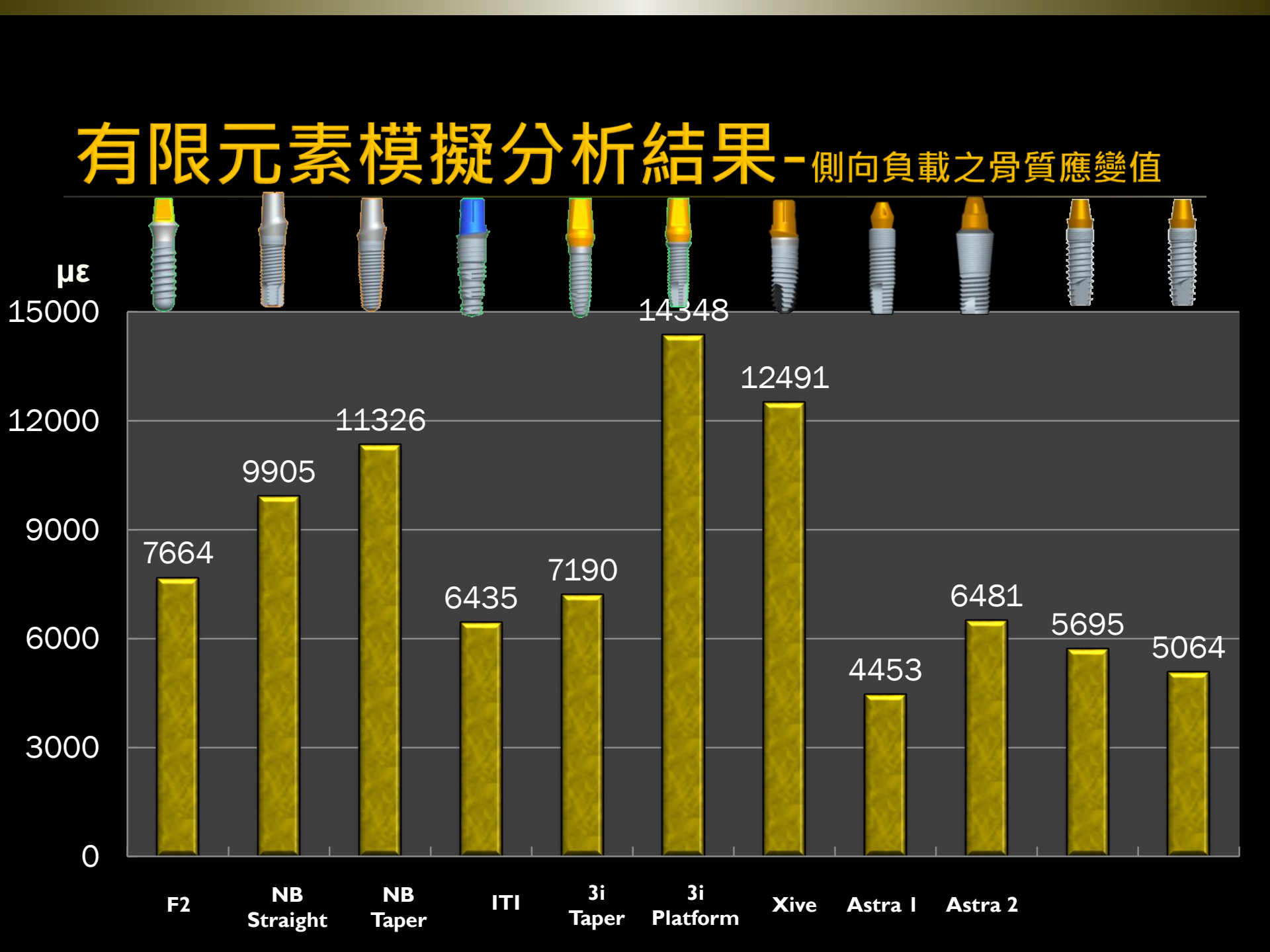
European Journal of Oral Sciences, Vol. 115, pp.408-416, 2007.

有限元素模擬分析結果(上顎)

- 骨質應變分佈圖-側向負載



有限元素模擬分析結果-側向負載之骨質應變值

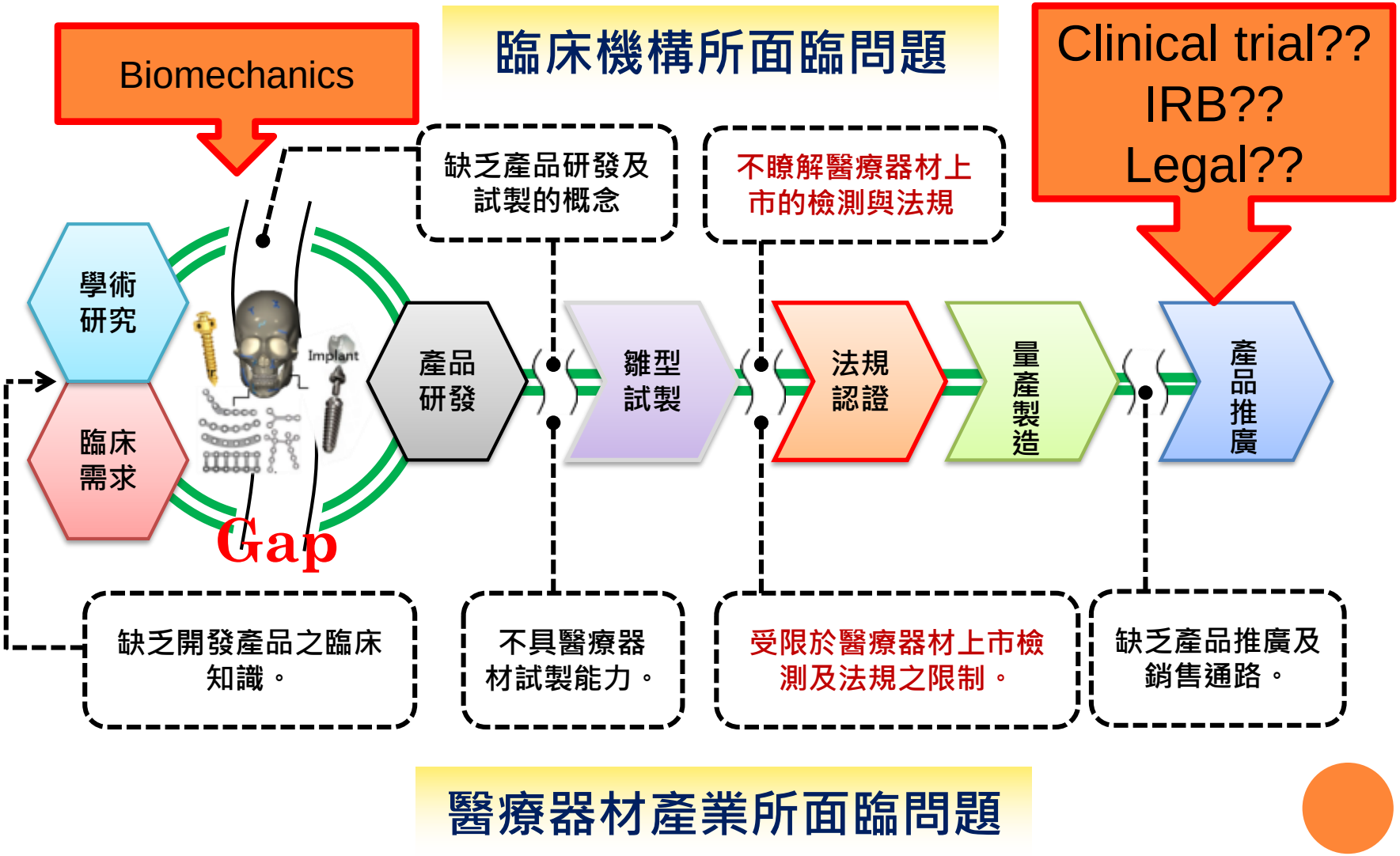


Summary of Current Medical Device Premarket Review Processes

Country	Premarket Review Documentation	Requirements	Recognized Standards
中華民國	查驗登記	醫療器材查驗登記準則/STED 體外診斷醫療器材查驗登記審查須知	衛生署醫療器材採認標準
United States	510(k) PMA STED Pilot	Substantial Equivalence/FDA Special Controls PMA+QS Inspection Essential Principles	FDA Recognized Standards
EU+EFTA	Technical File Review	AIMD/MDD/IVDD Essential Principles Annex II: Full QS	Harmonized Standards
Australia	GHTF MD STED GHTF IVD STED	Essential Principles	TGA Recognized Standards
Canada	Technical File STED (III & IV)	Essential Principles	Health Canada Recognized Standards
Japan	醫療機器承認審查 STED (III & IV)	醫療機器基本要件(Essential Requirements)	認證基準 承認基準 醫療機器審查指南 JIS

資料來源：工研院量測中心醫療器材驗證室

產業現況與問題-高階醫材(Class II, III)產業缺口與解決方案



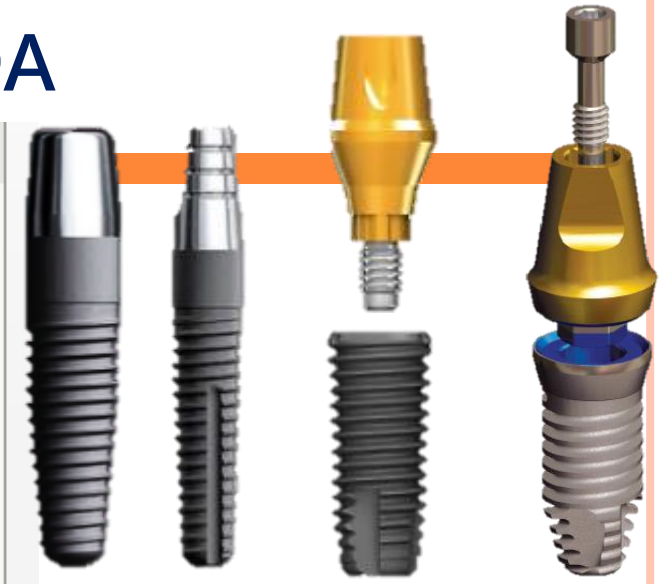

Optimal? Biomechanics (CAE/FEA)?

探討臨床參數不夠多?

Dental Implant Approval by FDA

New Search | Back To Search Results

Device Classification Name	Implant, Endosseous, Root-Form
510(K) Number	K122664
Device Name	ZUGA DENTAL IMPLANT SYSTEM
Original Applicant	ZUGA MEDICAL, INC. P.o. Box 566 Chesterland, OH 44026 2141
Original Contact	Karen E Warden, Phd
Regulation Number	872.3640
Classification Product Code	DZE
Subsequent Product Code	NHA
Date Received	08/31/2012
Decision Date	[illegible]
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Dental
Review Advisory Committee	Dental
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No
Combination Product	No



1 piece 2 piece 3 piece

New Search | Back To Search Results

Device	Implant, Endosseous, Root-Form
Regulation Description	Endosseous dental implant.
Regulation Medical Specialty	Dental
Review Panel	Dental
Product Code	DZE
Submission Type	510(k)
Regulation Number	872.3640
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Recognized Consensus Standards

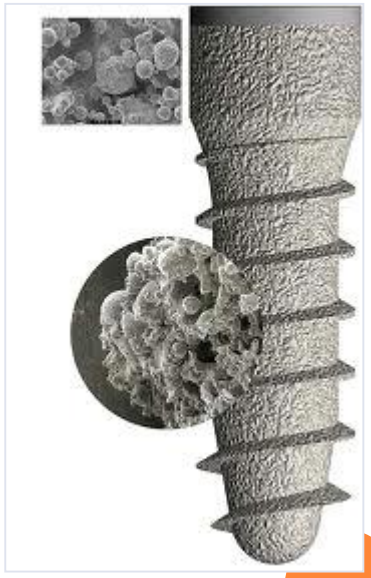
- ISO 10993-14 First edition 2001-11-15 Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics
- ISO 14801 Second edition 2007-11-15 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants
- ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
- ASTM F2024-10 Standard Practice for X-Ray Diffraction Determination of Phase Content of Plasma-Sprayed Hydroxyapatite Coatings
- AAMI/ANSI/ISO 10993-14:2001/(R) 2011 Biological evaluation of medical devices - Part 14:

Dental Implant Approval by FDA

- Mechanical：ISO 14801
- Biocompatibility：ISO 7405, ISO 10993
- Coating：ASTM F2024-10,ASTM F1377-08
- Forging： ISO 5832-2, ISO 5832-3, ISO 5832-11
- Ceramic：ISO 9693, ISO 10993-14

力學測試

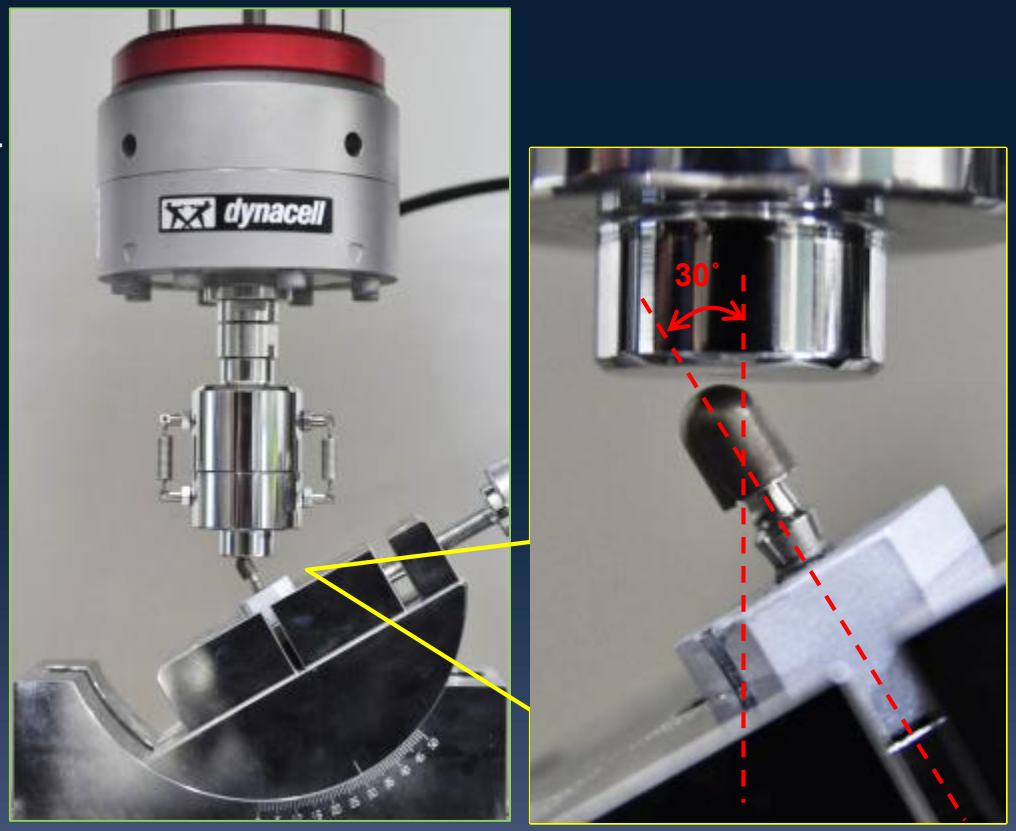
材料測試



塗層及生物相容性測試

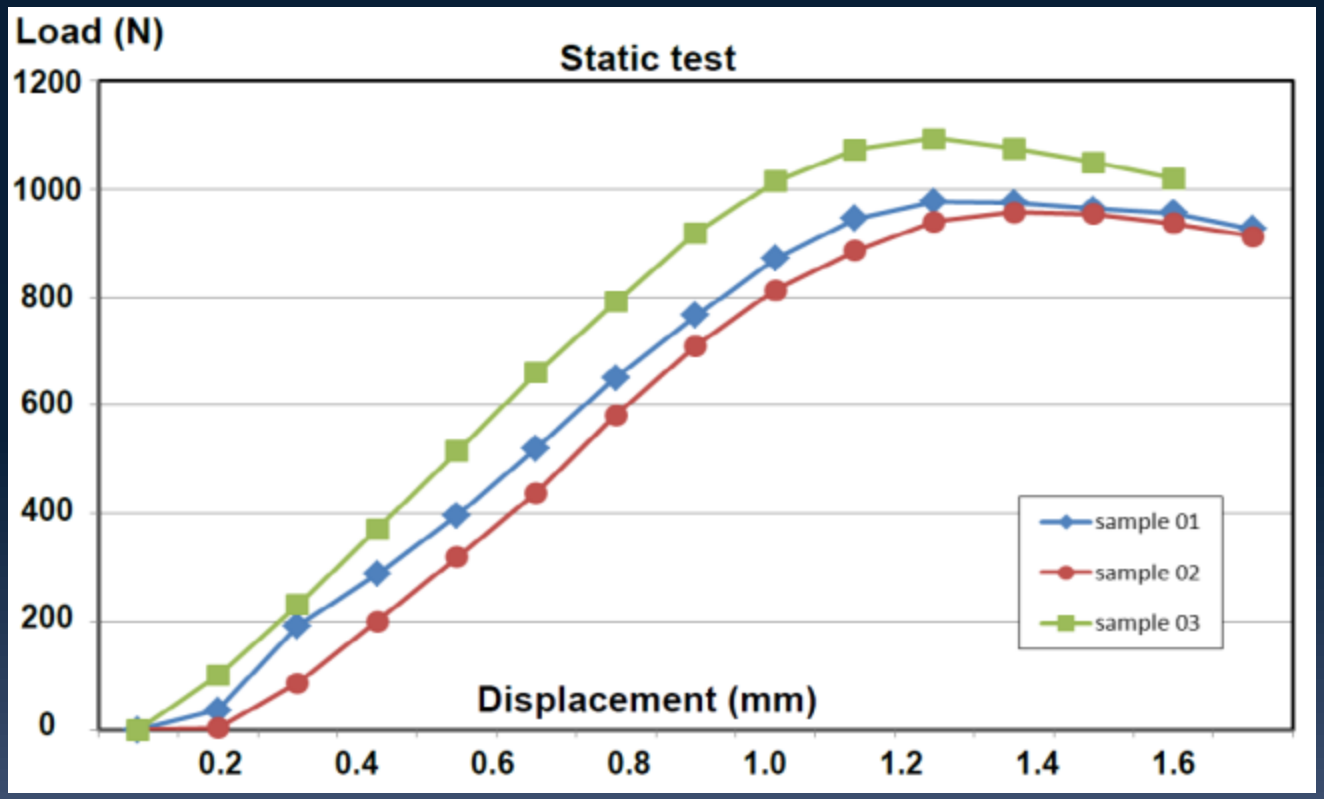
Dental Implant Fatigue Test-ISO14801

- **Purpose：Life limitation**
- **Machine：Fit ISO 7500-1及 ISO 4965 (accuracy)**
- **Setup：**
  - **Incline 30 degree**
  - **Embedding material>3GPa**
- **Static test：**
  - **Load：1 min/mm**
- **Fatigue test：**
  - **80%,70%,60%,50%,40% of Static fracture load**
  - **Sine wave**
  - **Frequency：15 HZ**
  - **Cycles：5,000,000 cycles**



Dental Implant Fatigue Test-ISO14801

- **Static testing**
  - **Failure load (N)**



Load-displacement

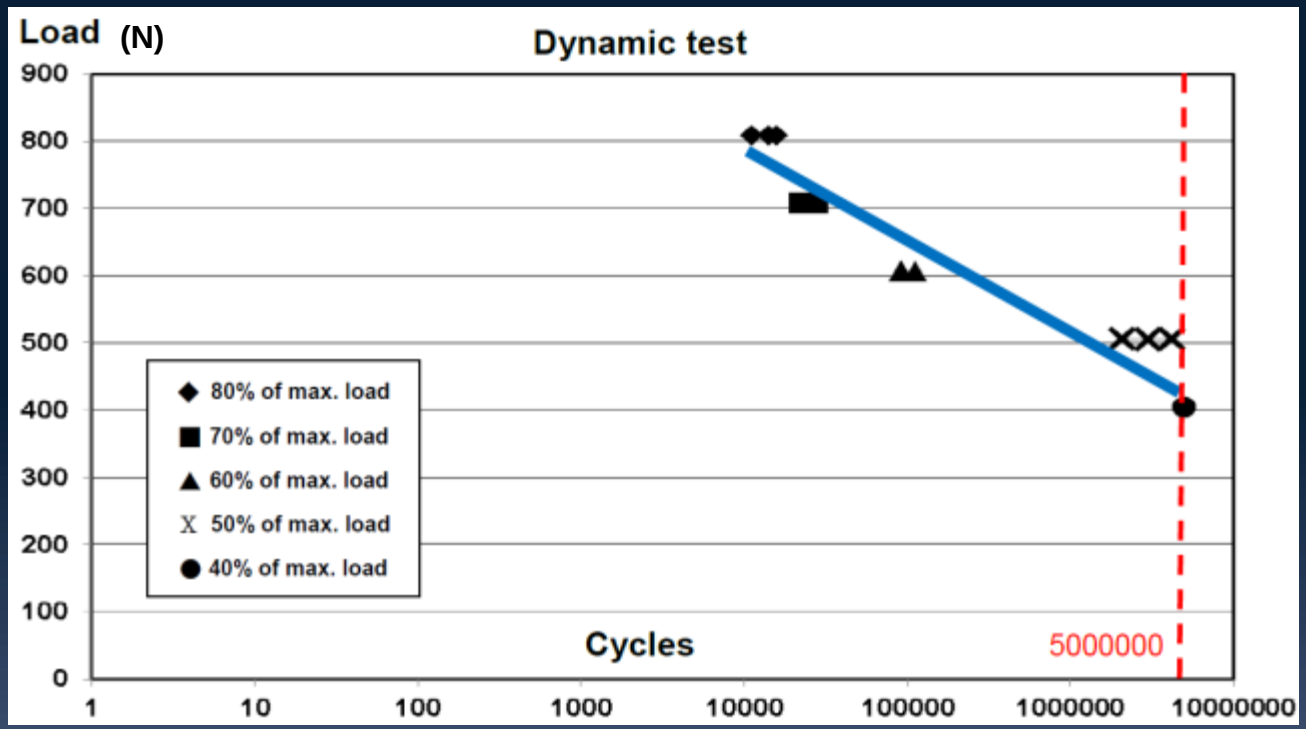
Fracture pattern

Dental Implant Fatigue Test-ISO14801

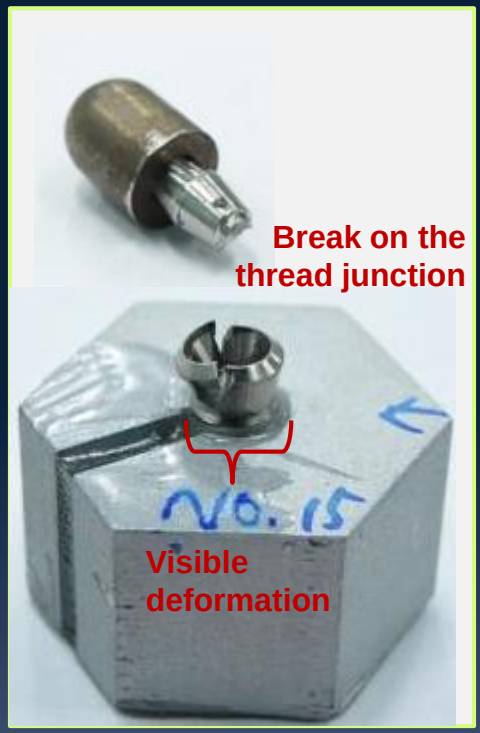
% of maximum load	Load /(Moment)	Number of cycles	Temp. / HMD.
80%	Between 80.9N to 809N/ (Between 445Nmm to 4450Nmm)	14309	21˚C / 71%
		11156	22˚C / 70%
		15765	22˚C / 70%
70%	Between 70.8N to 708N/ (Between 389Nmm to 3894Nmm)	24446	22˚C / 70%
		27809	22˚C / 70%
		22065	22˚C / 70%
60%	Between 60.7N to 607N/ (Between 334Nmm to 3339Nmm)	91839	26˚C / 61%
		112279	26˚C / 59%
		92904	28˚C / 57%
50%	Between 50.6N to 506N/ (Between 278Nmm to 2783Nmm)	2987597	28˚C / 57.5%
		4188494	27˚C / 58%
		2062882	24˚C / 60.5%
40%	Between 40.5N to 405N/ (Between 223Nmm to 2228Nmm)	5000000 (pass)	25˚C / 68%
		5000000 (pass)	21˚C / 58%
		5000000 (pass)	25˚C / 58%

Dental Implant Fatigue Test-ISO14801

- **Fatigue testing**
  - **Life-time figure**



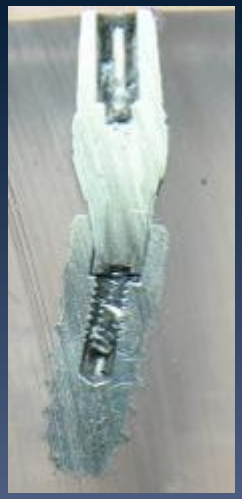
疲勞壽命曲線圖



動態負載後試件

ISO14801—static test (6 cycles)

第一版	第二版	第三版
Abutment 純鈦	Abutment 鈦合金	Abutment 鈦合金
Abutment Screw 純鈦	Abutment Screw 純鈦	Abutment Screw 鈦合金
Fixture 純鈦	Fixture 純鈦	Fixture 純鈦



第四版

1. fixture長度縮短為9mm

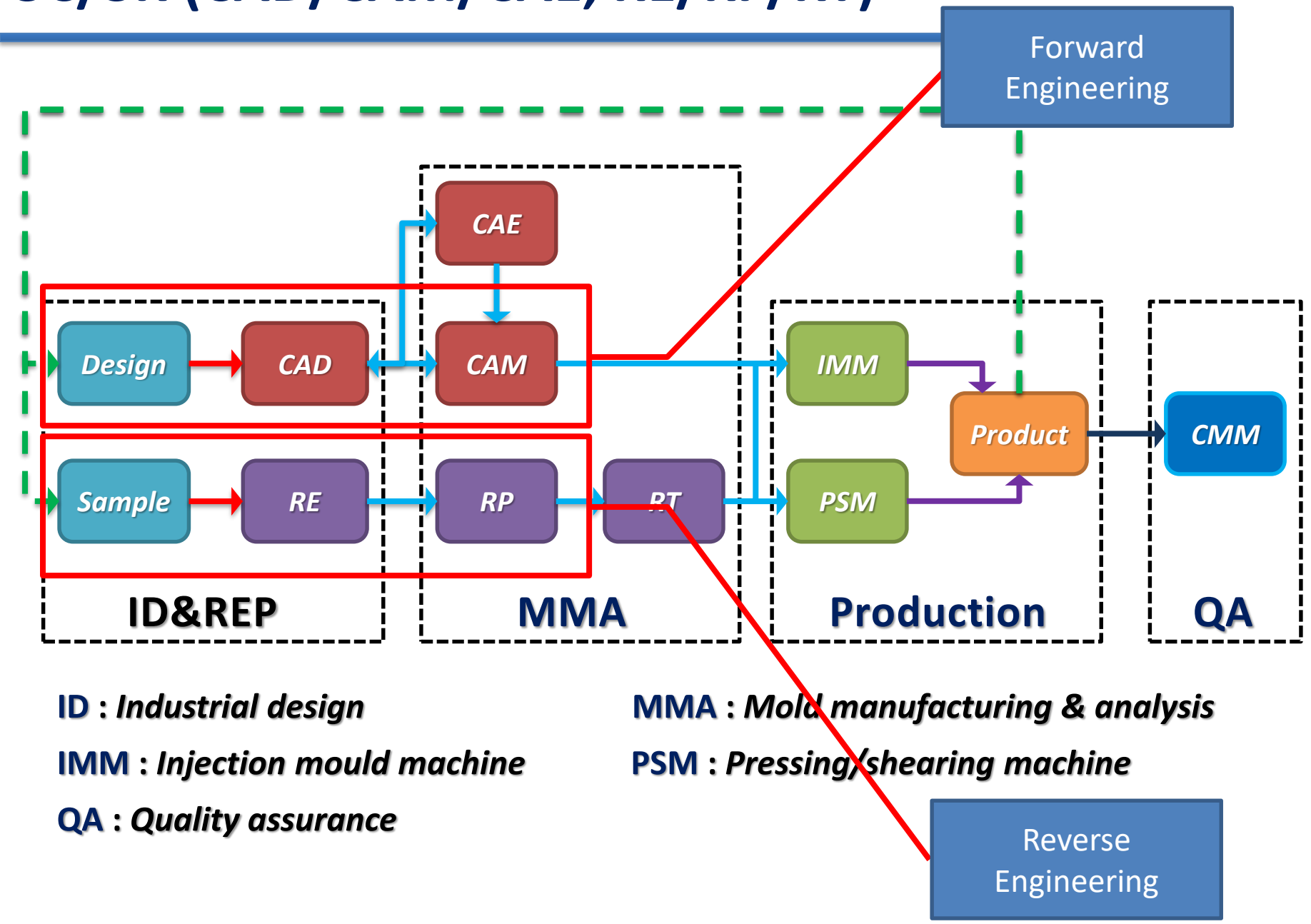
第五版

1.植體外徑由3.45mm增加至3.6mm。
2. 粗細螺紋交接處，增加粗螺紋之 內徑(即加工時提早收刀)。

第六版

1.增加abutment腰身厚度20條。
2. 將abutment/fixture接合向下再深入約1mm (即fixture的morse taper壁側單邊往外擴0.15mm，可將abutment向下移)。

3C/3R (CAD/CAM/CAE, RE/RP/RT)



ID : *Industrial design*

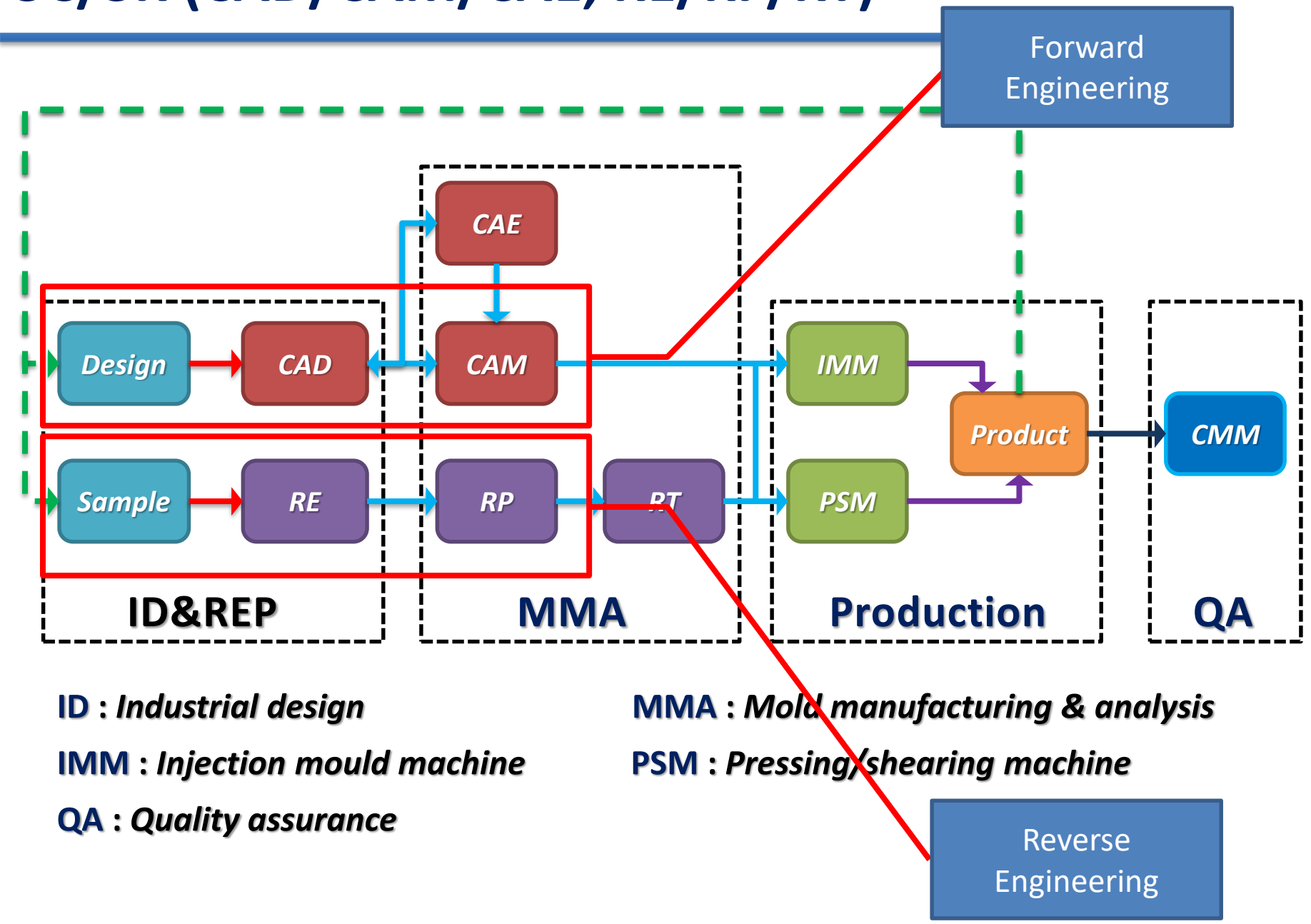
IMM : *Injection mould machine*

QA : *Quality assurance*

MMA : *Mold manufacturing & analysis*

PSM : *Pressing/shearing machine*

3C/3R (CAD/CAM/CAE, RE/RP/RT)



ID : *Industrial design*

IMM : *Injection mould machine*

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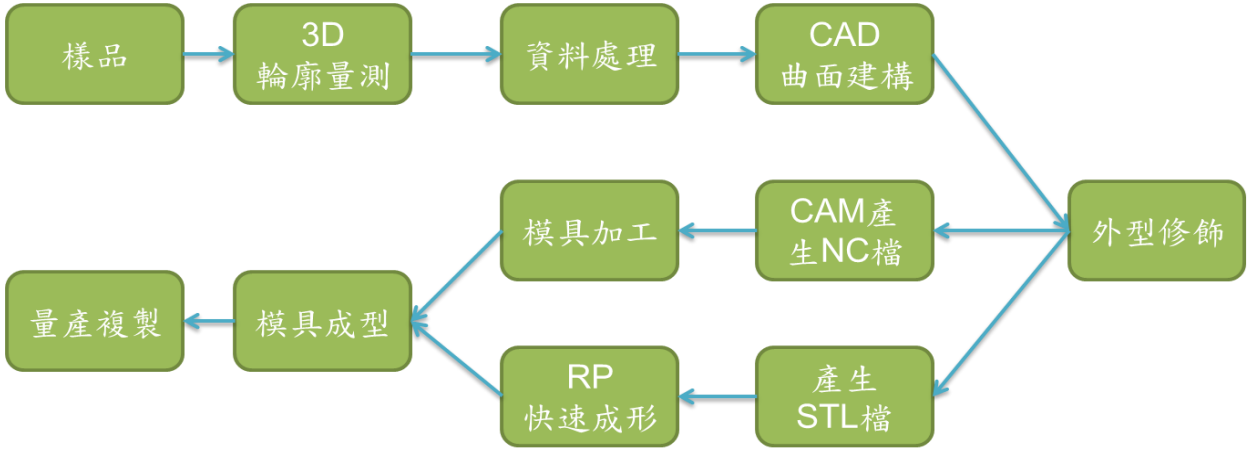
3R

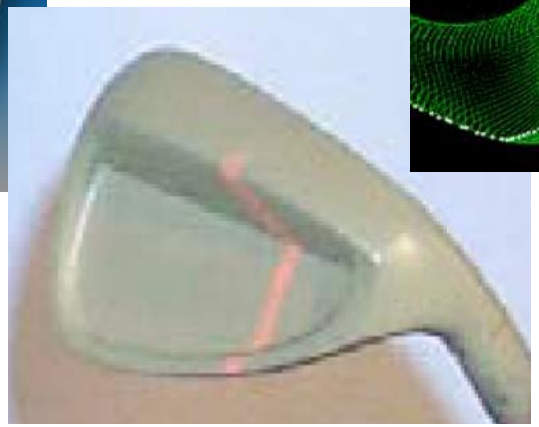
- **Reverse Engineering**

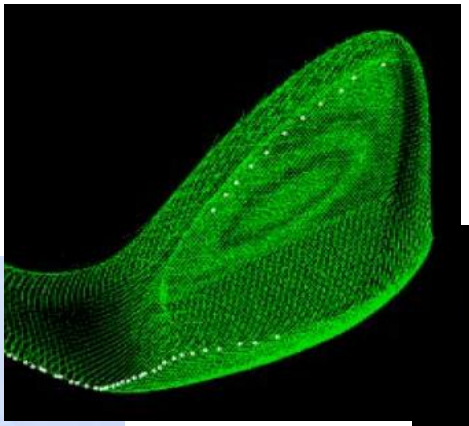
RE → RP → RT

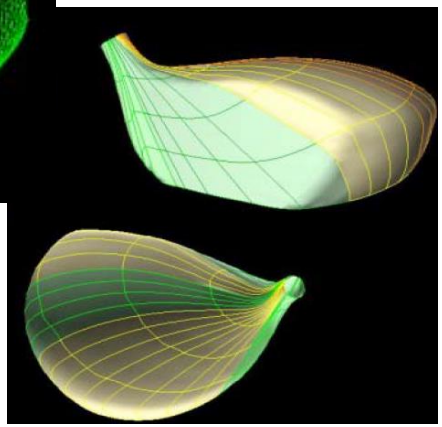
3R (RE/RP/RT)

❖ 逆向工程(Reverse Engineering)







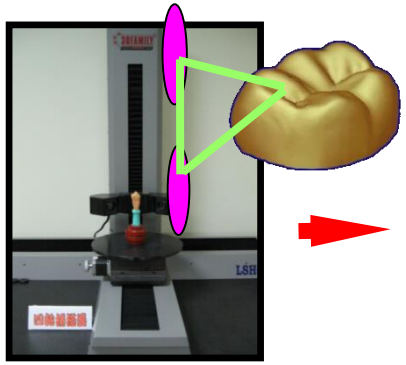


3R (RE/RP/RT)

❖ 逆向工程(Reverse Engineering)

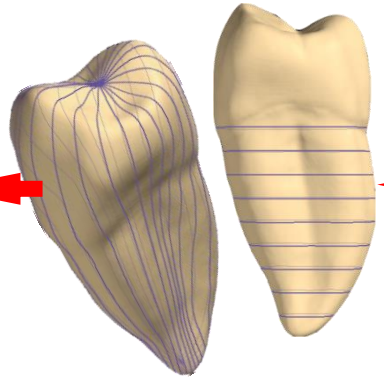
實體樣品 → 影像掃描 (Laser scanner, CT etc.) → 輪廓擷取 (點、線、面) → 影像編修重組

小白齒模型

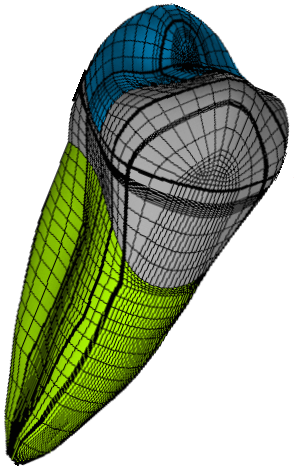


雷射掃描

小白齒點資料

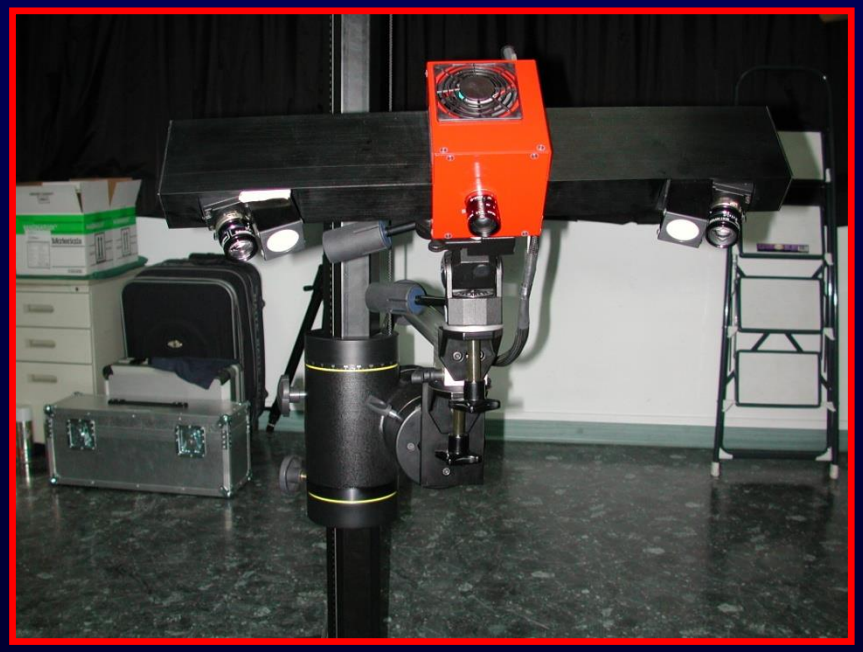


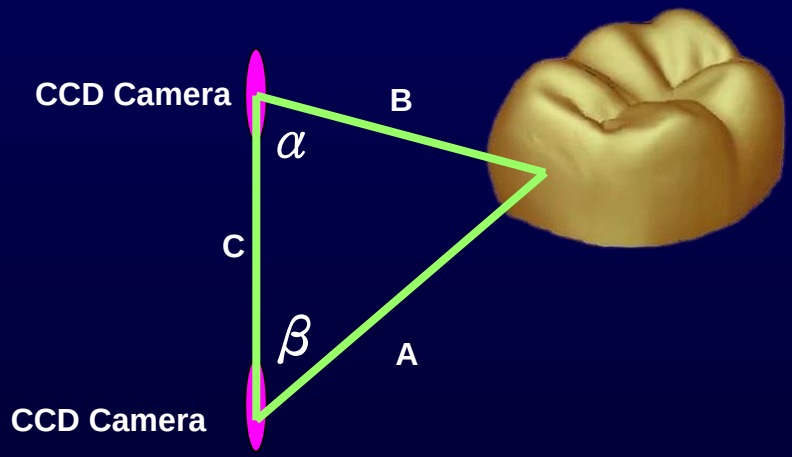
輪廓線截取



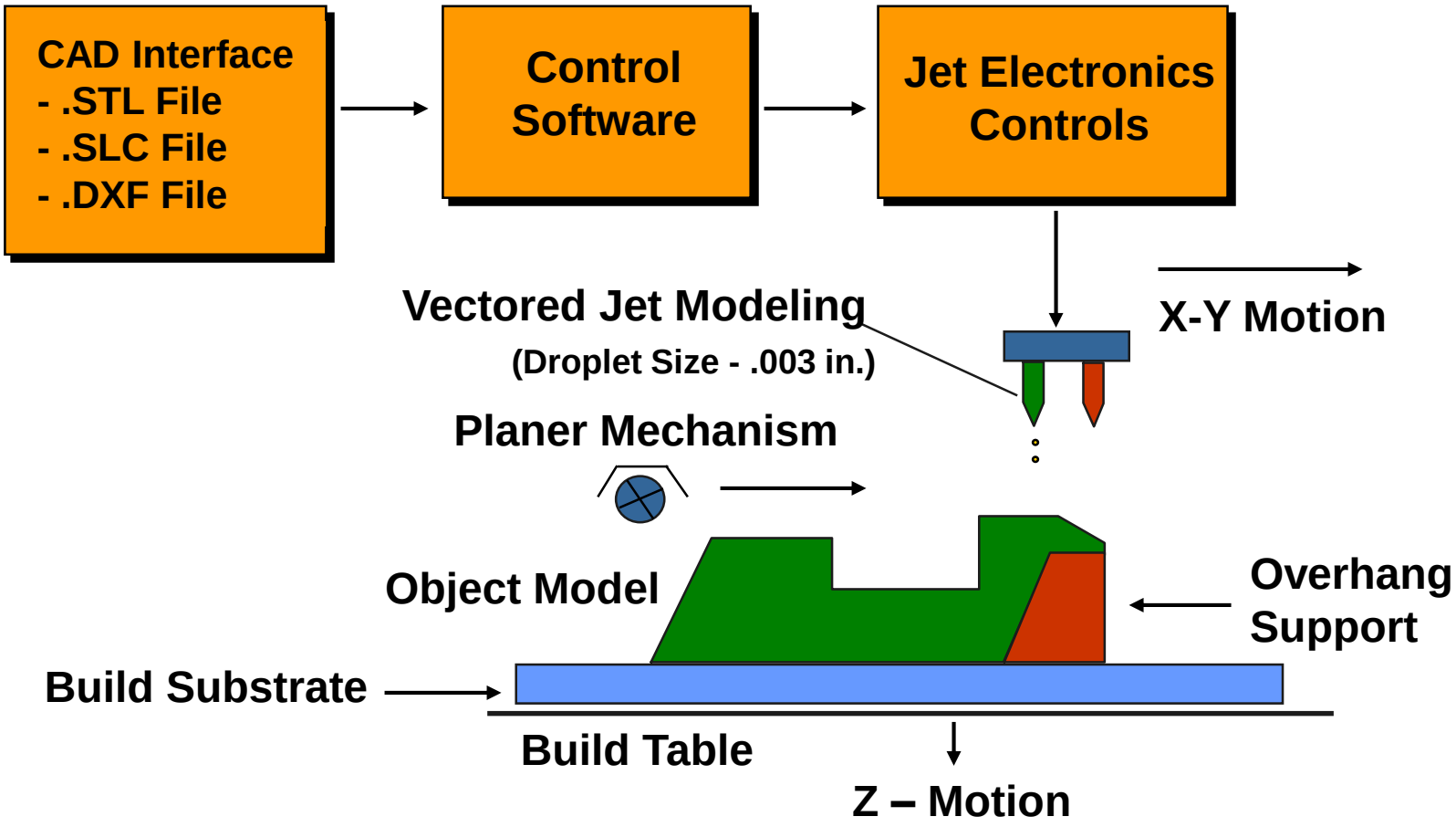
RE

- 3D geometry/shape measuring
  - Laser, CCD, CT, Micro-CT, Dental-CT





RP build process



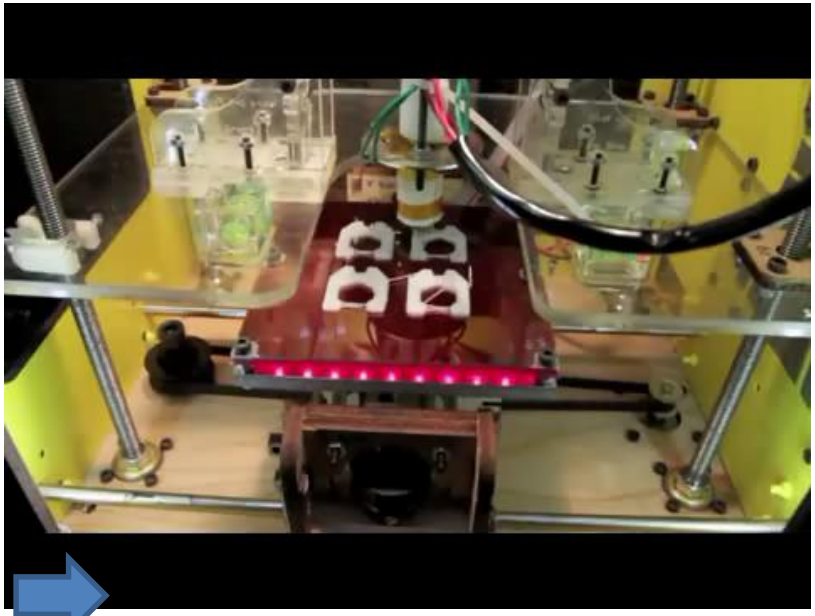
3R (RE/RP/RT)

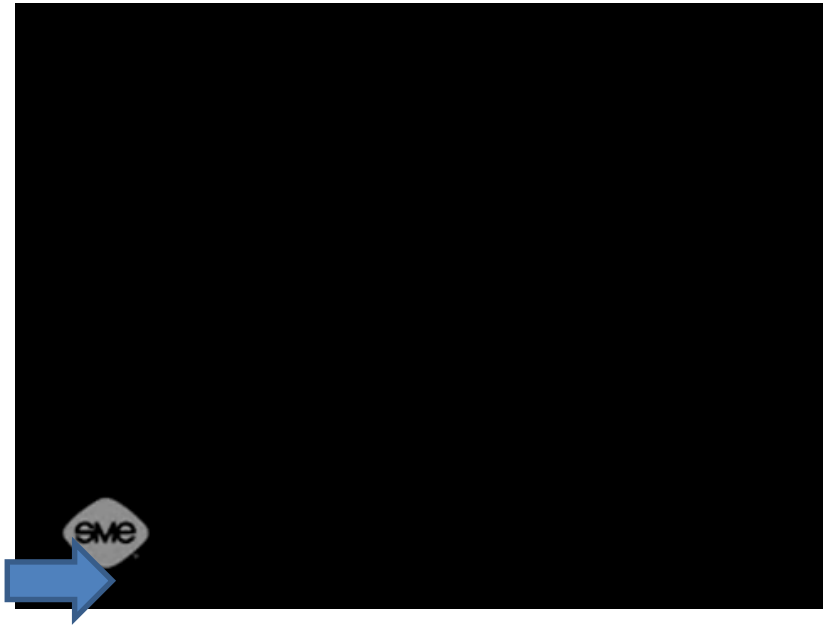
❖ 快速成形(Rapid prototype)

模型3D設計 → 轉成.stl檔 → 產生加工程式 → RP快速成形

❖ 快速模具(Rapid Tooling)

原始母型 → 模具製造設計 → 灌模 → 脫模



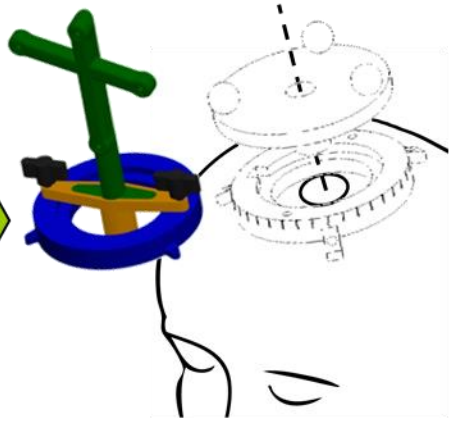


3R (RE/RP/RT) clinical application

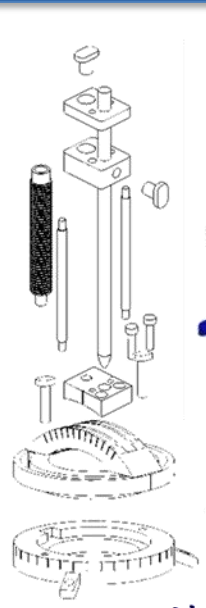
❖神經外科手術燒灼針三維定位架

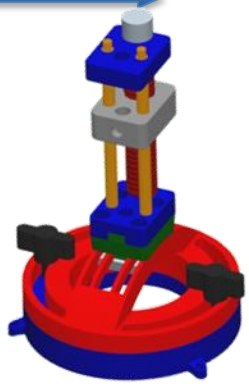
腦組織病灶CT影像

CAD機構設計

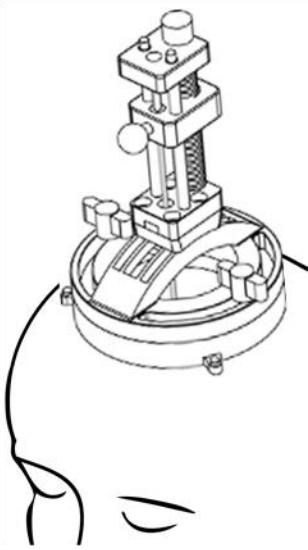


傷口導正對位



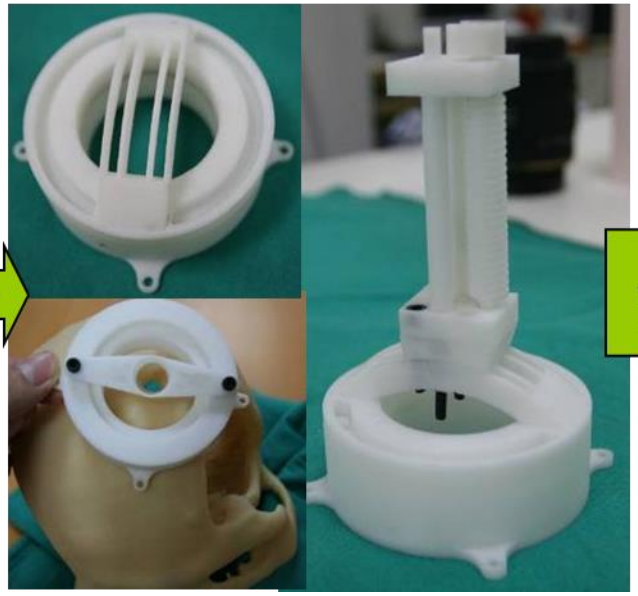


6DOF

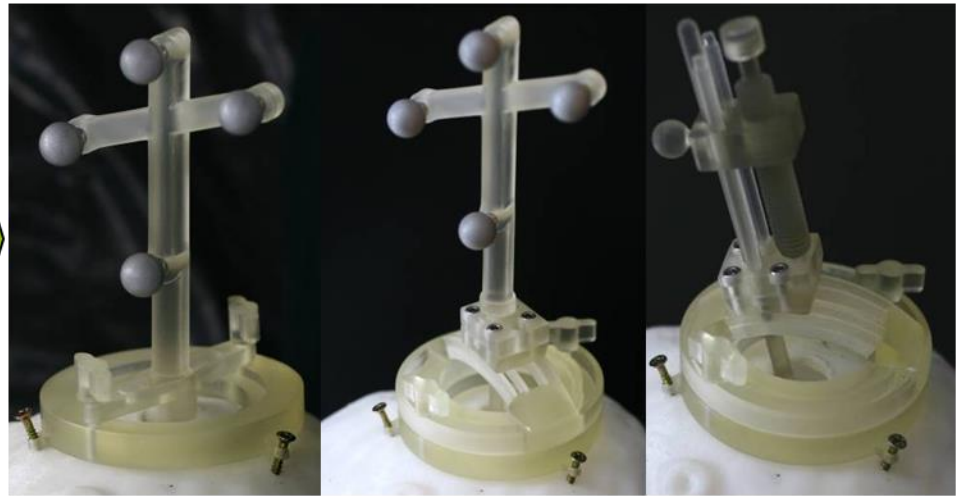


燒灼針定位微調侵入

RP

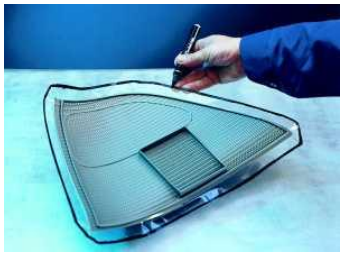


In vitro test



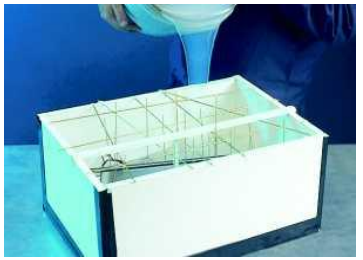
RT slicone molding process

Create Master Pattern

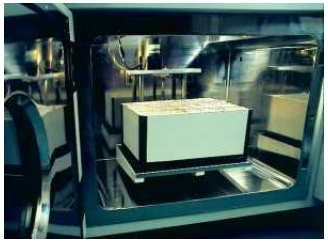


Create Parting Line

Add Gating



Pour Silicone

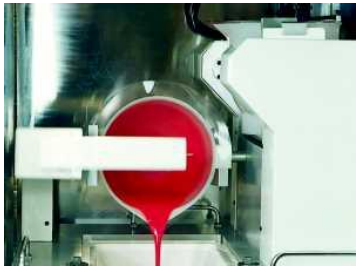


Vacuum Cast

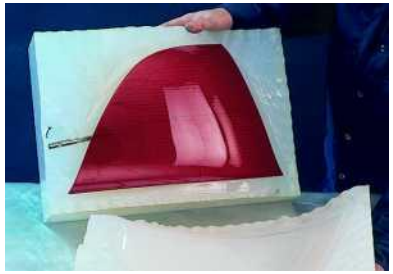
Split Mold

Remove Master Pattern

Close Mold



Cast Urathane



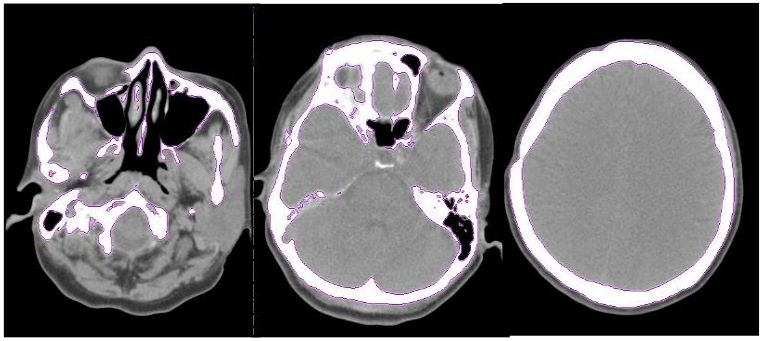
Remove Part

Remove Gating

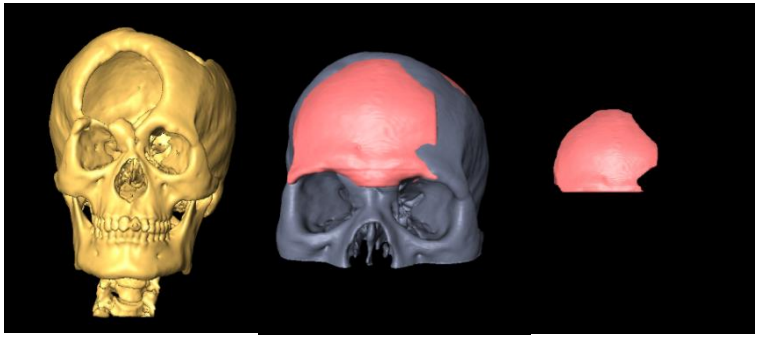
3R (RE/RP/RT) clinical application

❖ RE/RP/RT之臨床應用

頭顱大範圍缺損



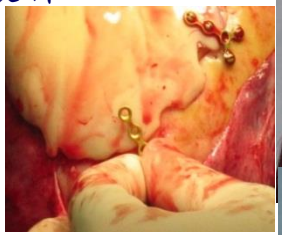
影像處理與重組



頭顱大範圍缺損補塊影像重建

補塊RP製作

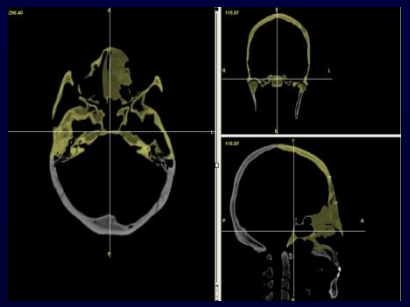
補塊RT製作

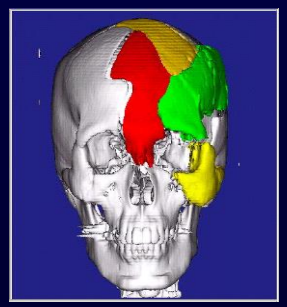


臨床應用

案例介紹

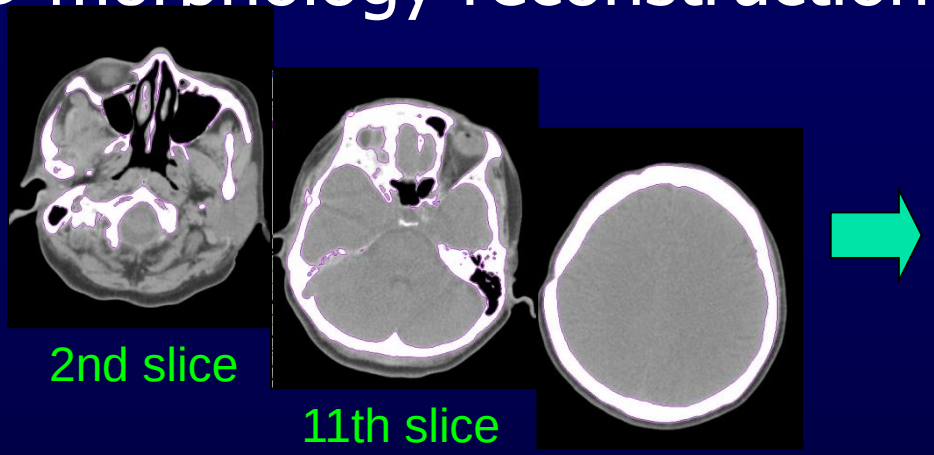
- 逆向工程及快速原型技術於顱骨大範圍缺陷重建

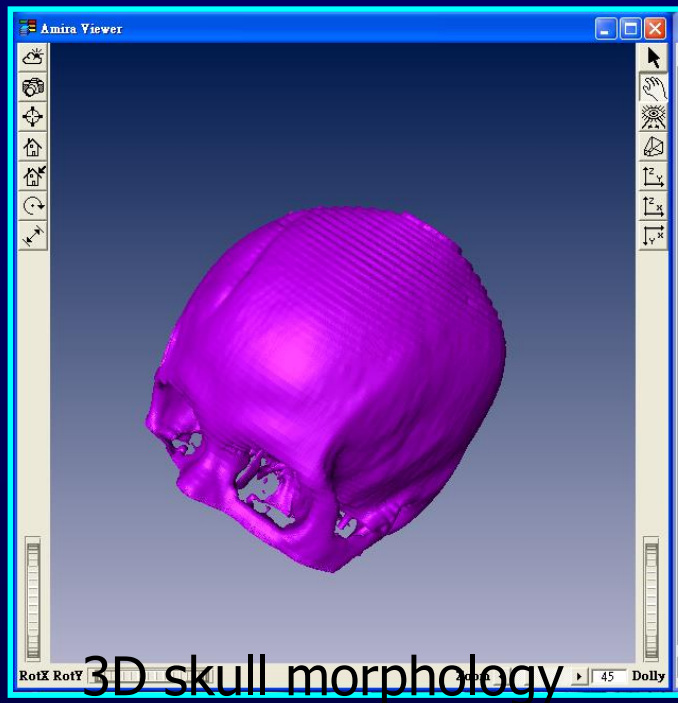




Reverse engineering (RE)

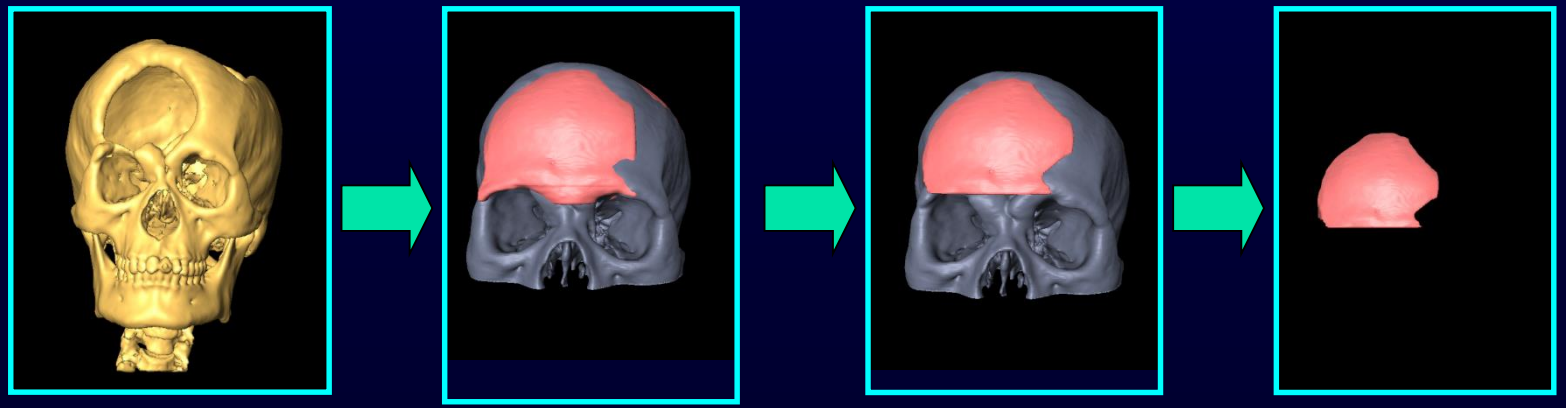
- Amira software
  - 3D morphology reconstruction



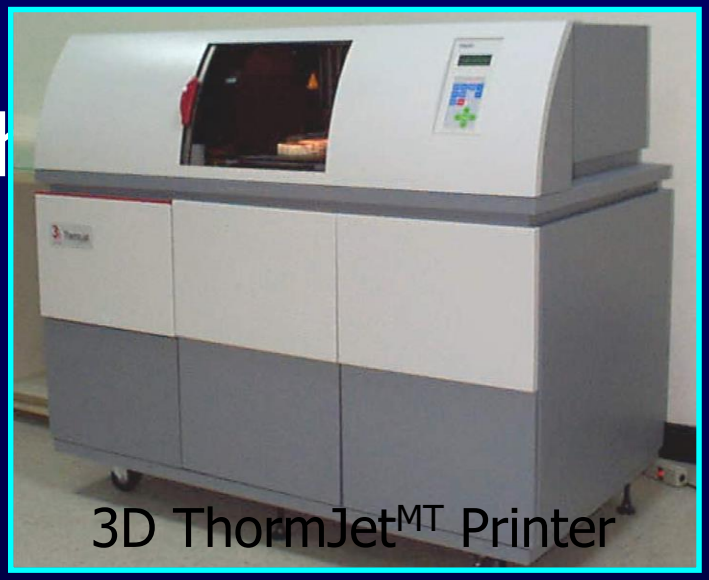


3D skull morphology

  - implant design

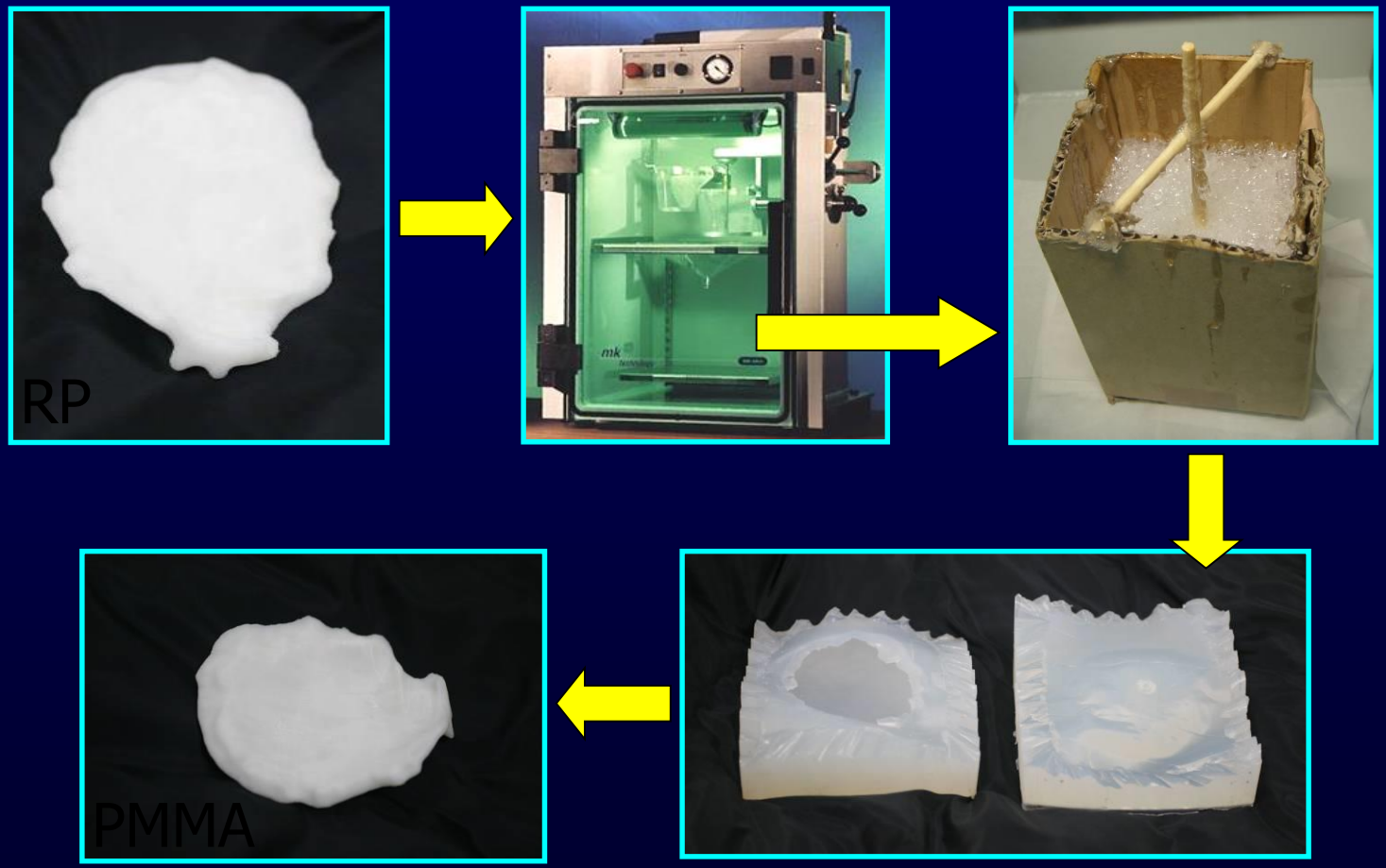


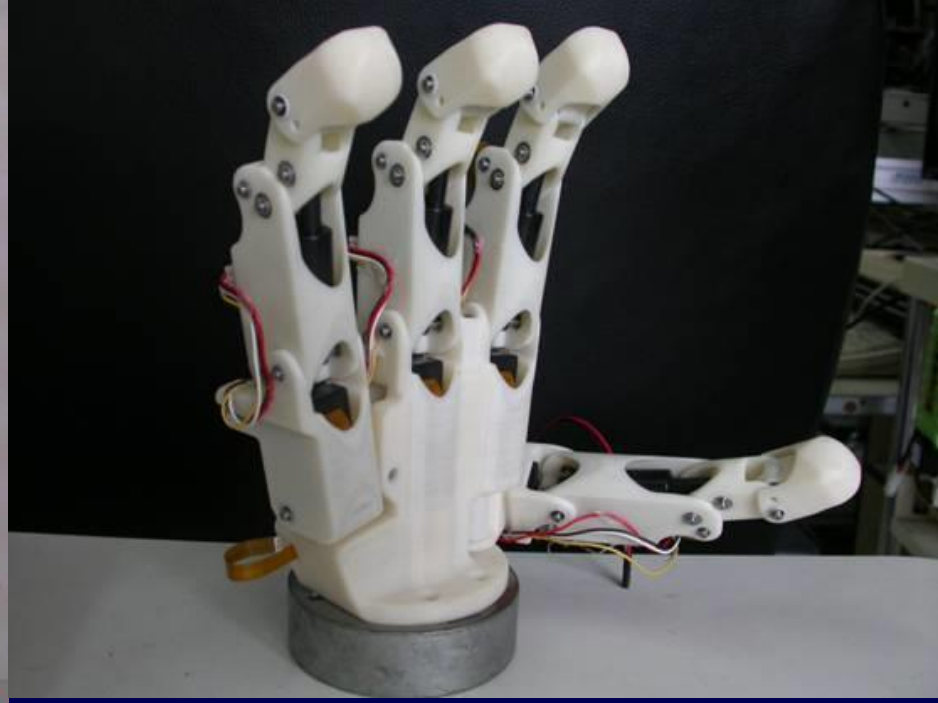
Rapid prototype (RP)



3D ThormJet^{MT} Printer

Rapid tooling (RT)





元智大學機械系陳傳生教授

- 機構元件所使用的FDM ABS工程材料，具有高強韌性、耐候不變形的特性，非常適合進行少量生產製作，工件可以當作成品使用。
- 對於設計人員而言，與傳統CNC相比，不需要任何加工經驗與技術，即可再電腦旁快速輸出各種機構設計元件，不受加工程序限制。
- 大幅縮短設計變更時間，上午設計變更完成，下午就能進行測試。