

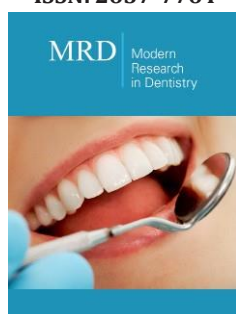
Pirmoji klinikinė patirtis su ICX-Active Master Implantų Sistema: 3 metų retrospektyvus tyrimas

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Santrauka

Tikslas: Šio retrospektyvaus tyrimo tikslas buvo pranešti apie klinikinę patirtį naudojant ICX-Active Master implantų sistemą. Implantų konstrukcija atitinka šiuolaikinės galutinių elementų modeliavimo išvadas. Tai atitinka minimalų kaulo įtempimą, glaudžiai susijusį su implantais.

Madžiagos ir metodai: šiame tyrime retrospektyviai įvertinti klinikiniai duomenys apie pacientus, gydytus ICX – Active Master implantų sistema. Pacientams buvo implantuoti bent po vieną implantą į viršutinį ar apatinį žandikaulį ir buvo naudojami ICX-Active Master, ICX-Narrow ir ICX-Active White implantai. Implantas pirmiausia tinka indikacijoms, kai implantas implantuojamas nedelsiant ir nedelsiant apkraunamas, ir tais atvejais kai kaulo prieinamumas yra prastesnės kokybės ir kiekio.

Rezultatas: autoriai įvertino patirtį su 500 implantų, įterptų į 4 skirtingas vietas nuo 18 iki 82 metų amžiaus. 125 vyrams buvo įstatyti 286 implantai, 105 moterims – 214 implantų. Implantai buvo naudojami visų rūšių kaulams (D1-D4). Implantų skersmenys buvo 3,3mm, 3,75 mm, 4,1mm, ir 4,8mm, ilgis 10mm, 12,5mm, 15mm. Šiuo metu vertinimo laikotarpis yra dveji metai su 100% sėkmės procentu.

Išvada: Nepaisant to, kad jis naudojamas ne tik pagal įprastines indikacijas, bet ir skubiose ar uždelstose indikacijose, įskaitant skubų implantavimą, Active Master tapo saugia ir tinkama alternatyva implantologijos srityje.

Raktiniai žodžiai: koncepcija aktyvi; osteointegracija, neatidėliotina implantacija, implantų užšaldymas.

Introduction

ICX-Active Master implant constitutes a consequent expansion of the ICX system portfolio from Medentis. This implant represents a fundamental simplification of the concept of immediate implantation, i.e., implantation which follows immediately after a tooth is extracted or lost due to injury. Immediate implantation also remains the first indication for this type of implant. Another strong point is the use of implants in bones which are compressed in terms of quality and availability. The unusually high primary stability (strength) of the implant frequently also allows its immediate loading. In addition to the standard diameters 3.75-4.1-4.8mm and lengths of implants 8-10-12.5-15mm, ICX-Active-Master Narrow implants are available with a diameter of 3.3mm. These come in three lengths 8-10-12.5mm. Whereas in view of the prosthetic supra-structure standard active implants are compatible with the ICX Premium system, Narrow active implants have a prosthetic range completely of their own. Ceramic implants (zirconium oxide, ZrO₂/Y-TZP) with diameter of 4,1mm and lengths 8-10-12.5mm constitute a separate range of active implants [1,2]. The long-term success of loaded implants depends on many factors.

These are derived for one thing from the individual clinical situation of the patient and also to a significant extent from the quality and special properties of the individual components of the implantology system. One of the important factors are the modalities of the edge surface

for the implant surfaces. The physical-chemical and morphological properties of the implant surface are also important. In general, it applies that the structuring of a surface or its working leads to an acceleration of the early healing processes and thus an increase in the quality of the healing process along with increase in the quality of direct contact between the implant and bone [3,4]. For a specific and verified ICX implant surface this involves a mechanical and thermochemical modification of this surface. A roughening and subsequent increase of this surface is achieved through this process. In the first step the surface is blast abraded with titanium corundum. In the next step the implant surface is exposed to the action of a strong acid in a special thermochemical process [3]. It has been generally demonstrated that compared with other implant surfaces of the same geometry surfaces treated in this way display the fundamental advantage of this combination of treatment compared with other surface treatments of implants. This process creates a three-dimensional microstructured surface representing the ideal physical, chemical and biological conditions for addition and growth (firstly addition) of the relevant cells responsible for the formation of new bone. This encourages and positively influences the formation of new bone. The joint between the bone and implant surface is stable, and the healing time is reduced. ICX implants are subject to strict quality control. The implant's surface topography and roughness are checked. Implants are subject to strict quality control using a scanning electron microscope. They must display very strict chemical purity during this check.

And this is verified regularly at two mutually independent facilities in Germany. There is also a quantitative analysis of the surface using optical profilometry (NanoFokus). As part of quality control there are also regular tests with cell cultures to ascertain the quality of the impact of the implant's material at the cellular level in the immediate surroundings. In general terms four mutually linked properties of the implants' surface were shown to have a direct impact on bone cells: chemical composition, energy, roughness and morphology of the surface. It was seen that the fixing and colonisation of the surface, and the consequent division and differentiation of these cells is influenced and modified by one or a combination of the aforementioned factors. The study of these processes results in a continuous improvement of the surface properties, such as hydrophilia or initial fixing of osteoblasts [5,6]. Another advantage of the ICX Active system is that if the surgical protocol is introduced and adhered to, there is no so-called "freezing" of the implant. Another important feature in this is the thread, which allows the implant to be moved back whilst adhering to the protocol. This range of implants has been created not only due to the great pressure on implantology for early and delayed solutions, but also with the possibility of conventional placement after sufficient healing of the bone.

Materials and Methods

Characteristics of system

The ICX-Active implant system has several characteristic elements

- A. Bevelled edge of implant, which should result in lower

stress in the area of the cortical bone and thus prevent and reduce resorption in this most important area of the implant

B. Aggressive thread for perfect primary stability, which is absolutely fundamental primarily for immediate and delayed implantation. This thread utilises a self-tapping double compression thread, and in spite of its "aggression" is very simple during placement - it guides the operator very precisely in the implantation osteotomy.

C. Type of thread: self-tapping double thread allows faster yet more sparing insertion of the implant

D. Combination of compressive and progressive type of thread. Whereas the angle of the compressive thread increases the stability of a conical implant through compression of bone particles, the self-tapping progressive thread on the apex of the implant's conical body allows subsequent fixing of the implant often in residual bone beyond the peak (end?) of the extraction socket. The progressive thread offers a significant increase in the contact surface of the implant with the surrounding bone in the aforementioned apical area with non-compressed bone.

E. Verified structured surface with hydrophilic properties allowing faster, quality healing of implant

F. All ICX implants are made of pure grade 4 titanium.

G. Abutment, its internal part complies with compatibility with the premium range without use of other components. The Narrow range constitutes an exception. The actual abutment combined with the implant has an anti-rotation element (hexagon) allowing the insertion and anchoring of the crown in a clearly given position. A self-locking angle is also used, which is significant in that it prevents the penetration of bacteria and so increases resilience against (one of the causes of) peri-implantitis.

The surgical protocol is a highly precise instruction for the insertion of an implant. It corresponds with the specifics of bone density, where it uses individual drills marked with either one, two or three bands. These

bands are a guide for the given bone density. This may seem pointless until the transplant dentist really feels differences in bone density. Another important thing is that the threads allow compression-increase in bone density. A screw-tap for densities 1 and 2 is essential. Another important element is that during the insertion of a dental implant we must not exceed 35Nm so that we can still manipulate the implant and so that we do not create a so-called frozen implant which is typical for some implantation systems. So, during manipulation we are capable of manipulating the implant up to a range of 20-25Nm of torque. Not adhering to these conditions leads to destruction of the implant insertion tool, which is dimensioned in such a way as not to destroy the anti-rotation elements of the implant when the torque limit is exceeded. The surgical protocol is different for immediate implants, where the procedure tends to be reduced by one or two steps back with regard to the seat following extraction preserving commensurate primary retention. It is similar for delayed implantation.

We talk of so-called under-preparation, where drills are used for a diameter smaller than the installed implant. Naturally for the healing of the implant we need at least 0.5mm of embedding under the corticalis, which goes hand in hand with the thickness-horizontal of the alveolus. Here the rule applies that if we get to a 1mm minimum bone thickness around the implant fixture, we try to drill up to 1-1,5mm deeper, because this corresponds to resorption, which is physiological with a smaller availability of bone in the area around the implant. It is possible to introduce the fixture with

Result

Table 1: Statistic data of inserted implants over a period of three years.

	Number of Implants	Maxilla (Upper Jaw)	Mandibula (Lower Jaw)	Augmentation	Immediate Implantation
Total	500	325	175	130	133
Men	286	154	132	69	71
Women	214	139	75	61	62



Figure 1: Delayed implantation for lateral incisor-subcrestal implantation.



Figure 2: Implantation jointly with bilateral sinus augmentation.

Over a period of three years the authors inserted 500 implants in 230 patients ranging from 18 to 82 years old. There were 286 implants in 125 men, and 214 implants in 105 women. Implants were used in indicative bone qualities from D1 to D4 in diameters 3.3mm, 3.75 mm, 4.1mm and 4.8mm in lengths of 10mm, 12.5mm and 15mm. The largest number of implants (nearly one third) were implanted in the gap after the loss of one tooth. Implants were used in

the aid of a mechanical device or manually with precise setting of torque. Manual insertion is a natural advantage for all implants. The actual implantation appears simple, but we might change the direction of insertion compared with the original pilot hole during installation, so an experienced implant dentist is required. But the strength (stability) of implant does not change with this shift in direction thanks to the type of threads. Naturally the system uses both analogous and navigated implantation.

indications solo abutment, shortened dental arch, joint of implants in fixed work in edentulous jaws and use of implants in edentulous jaws with hybrid transfer attachments. Implants were used for solo abutments in the main in indications of immediate or delayed implantation. The indication areas include sinus augmentation (sinus lift) in a single phase with implantation. Statistically speaking no implant was rejected (Table 1). In the case of an implant talk of prosthetic flexibility, which includes interchangeability of supra-structures between the Active system and Premium (conventional) system. Also, adaptation to the required direction in spite of other preparation osteotomy and finally use of screwable and cemented work, moreover with hybrid transfer (Figure 1-4).



Figure 3: Ceramic implant from in situ after insertion.

Diskusija

ICX Active Master sistema priklauso ICX implantų sisteminei grupei. Viena iš serijų yra Premium kurioje naudojamas osteotominis sriegis mažina stresą kortikalinėje srityje ir tai yra vienas iš privalumų. Čia yra galimybė palyginti Nobel Active arba Astra sistema, kurios turi panašius konstrukcijos ir naudojimo parametrus [7-10]. Tik finansinis aspektas, įskaitant ir kitas priemones, šiuo metu mažina šios sistemos pardavimo rinkoje galimybes. Taip pat galima palyginti su Neodent Drive, kilusia iš Brazilijos ir nuo 2015 m. vadinama Straumann [12,13]. Ši sistema finansiniu požiūriu yra panaši į ICX sistemą, visų pirma vienkartinio instrumento rinkinys, skirtas visai Neodent asortimentinei grupei. Vienintelė problema yra ta, kad jo negalima

naudoti kaulų tankio 1 ir iš dalies taip pat 2, nes nėra tokiam naudojimui skirtų srieginių užsukimų. Ši serija skirta tik viršutiniam žandikauliui ir šia nėra didelio pavojaus, kad įdėjus implantą jis "užšals". Daug kas priklauso nuo implantuojančio odontologo patirties. Apskritai galima sakyti, kad sistema ICX Active yra implantų asortimentas, kuriuose naudojant mikropluošto elementus – ICX Premium ir ploni "Slim Boy" implantai, skirti tam tikram plonam alveolės tipui, taip pat naudojami antstatų įtvirtinimui be siūlų, kuris yra labai naudingas emelementas nuo periimplantito. ICX sistemoje suprastruktūros sujungimui naudojami antirotaciniai elementai ir savaiminio fiksavimo kampo elementai, kurie sumažina bakterijų kolonizaciją ir taip užkerta kelią periimplantitui [14,15]. Panašius elementus turi sistemos Ankylos, Astra Tech. O šis savaime užsifikuojantis kampas leidžia perduoti spaudimą didesniame plote nei tik per suprustuktūros sriegį. Tai svarbu sujungimo tvirtumui be galimybės jį pažeisti ar sulaužyti. Šiuo metu egzistuoja kelios implantavimui skirtos medžiagos, tarp kurių yra įprastos titano, titano lydiniai kartu su cirkoniu ir titanu, beta titano lydiniai ir galiausiai keraminiai implantai [16-23]. Viskam atliekami biologiniai tyrimai ir mechaniniai – fiziniai bandymai, kad būtų laikomasi griežčiausių kauluose naudojamų medžiagų biologinio suderinamumo parametru. Su tuo susijęs ir suprastruktūrų, dažniausiai įterptų į implanto tvirtinimą, naudojimas. Šiuo atveju pirmenybė teikiama tvirtinimui naudojant elementus, apsaugančius nuo sukimosi ir labai dažnai savaime užsiblokuojantį kampą, kad būtų išvengta bakterijų kolonizacijos kortikaliniame sluoksnyje [24-26]. Kuriant implantus šiuo metu pirmoji faktinė konstrukcijos analizė atliekama galinių elementų metodu. Tai apima ne tik implanto projektavimą, bet ir aplinkos į kurią įdedamas implantas, modeliavimą [27-30] (5pav.).



Figure 4: Active Master implants 1,5 years after implantation.

Šiuo atveju svarbiausia implanto dalis yra kortikaliniame kaulo sluoksnyje, todėl čia svarbiausia sumažinti kaulo ir implanto įtampą, kad implanto kaklelio vietoje nebūtų nepageidaujamos kaulo rezorbcijos. Apskritai pagal galutinių elementų modeliavimą, t.y. atliktas streso tyrimas viso implanto srityje, geriausiai tinka nuolydis link stačiakampio implanto užbaigimo galvutės dalyjies. Taip pat taikoma, kad implanto paviršiaus susiaurėjimas tvirtinimo atžvilgiu implanto dalis, kuri dėl to yra platesnė, yra svarbi siekiant sumažinti spaudimą kortikaliniame srityje ir taip sumažinant rezorbcijos procesą [31,32]. Žinoma, turime atsižvelgti į tai, kad modeliavimas padeda kuriant kuo idualesnės konstrukcijos

implantams, tačiau kaulas, kaip gyvas organas, gali reaguoti kitaip, nei reagavo modeliavimo metu. Tai atitinka, pavyzdžiui, implanto kampą, implanto skersmenį ir koku būdu įsriegtų implantų įtempimą tam tikru kampu. Tai akivaizdu apatiniame žandikaulyje, kur mažesnio skersmens implantai neturi tokios rezorbcijos kaip modeliuojant galinių elementų metodu.

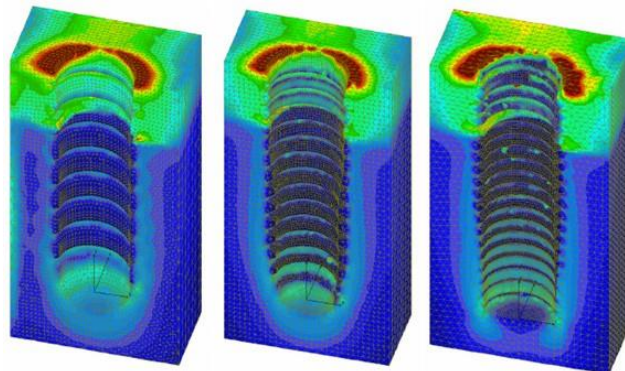


Figure 5: Illustration of modelling of final elements with use of various types of threads.

Išvados

ICX Active Master yra moderni, lanksti sistema, apimanti visą indikacijų spektrą, pradedant įprastine indikacija ir baigiant iki skubios implantacijos, įskaitant skubų implanto įkrovimą. Chirurginio protokolo dėka implantacija yra labai paprasta, tik reikia tam tikro dėmesio implantavimo metu, kai implantas gali pakeisti įdėjimo kryptį nuo implanto paruošto pagrindo. Implantų sriegis leidžia gerokai suspausti kaulą ir taip padidina kaulo tankį įdėjimo metu. Keraminiai vienfaziai implantai taip pat įeina į Active sistemos asortimentą.

Klinikinio naudojimo metu šios sistemos sėkmės rodiklis buvo 100% statistiniu vertinimu per trumpą trejų metų laikotarpį. ICX implantų paviršius išsiskiria optimaliu ir atkuriamu paviršiumiaus topografija. Iki klinikiniai ir klinikiniai duomenys rodo, kad paviršiaus šlifavimo ir ęsdinimo derinys, kaip ICX sistemos atveju, pasižymi puikia osteointegracijos savybe. Jei prie to pridėsime daugybę teigiamų klinikinių sistemos veiksmų, ICX sistema yra saugi ir patikrinta alternatyva implantuojančiam gydytojui.

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