



UNIwersytet Medyczny IM. PIASTÓW ŚLĄSKICH WE WROCLAWIU

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Ocena porównawcza stabilizacji dwóch rodzajów implantów zębowych o różnej średnicy platformy w stosunku do wczesnego i funkcjonalnego ich obciążenia

Comparative evaluation of the stabilization of two types of dental implants with different platform diameters in relation to their early and functional loading

Rozprawa na stopień doktora nauk medycznych

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1. Krawiec M, Hadzik J, Dominiak M, Grzebieluch W, Błaszczyszyn A, Kubasiewicz-Ross P. Early loading of titanium dental implants with hydroxyl ion modified surface: a 12-month prospective clinical trial. *Applied Sciences-Basel*. 2021;11(7):art. doi:10.3390/app11072958. **IF= 2,679, MEiN/KBN:100 pkt**
2. Krawiec M, Hadzik J, Olchowy C, Dominiak M, Kubasiewicz-Ross P. Aesthetic outcomes of early occlusal loaded SLA dental implants with hydroxyl ion modified surface - a 12 months prospective study. *Materials*. 2021;14(21):art. doi:10.3390/ma14216353. **IF= 3,623, MEiN/KBN:140 pkt**
3. Krawiec M, Olchowy C, Kubasiewicz-Ross P, Hadzik J, Dominiak M. Role of implant loading time in the prevention of marginal bone loss after implant-supported restorations: A targeted review [published online as ahead of print on May 24, 2022]. *Dent Med Probl*. doi:10.17219/dmp/150111. **MEiN/KBN: 70 pkt**

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Każde z uwzględnionych badań zostało wykonane przez Macieja Krawca, pod nadzorem merytorycznym prof. dr hab. Marzeny Dominiak, w Katedrze i Zakładzie Chirurgii Stomatologicznej. Indywidualny wkład autora w tworzenie powyższych badań i artykułów opisano w rozdziale III.

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WYKAZ UŻYWANYCH SKRÓTÓW

MBL- (Marginal Bone Loss)- utrata kości brzeżnej

BIC- (Bone to Implant Contact)- kontakt kości z implantem

API- (Approximal Plaque Index)- aproksymalny wskaźnik płytki

HKT- (Height of Keratinized Tissue)- wysokość dziąsła zrogowaciałego

TKT- (Thickness of Keratinized Tissue)- grubość dziąsła zrogowaciałego

PPD- (Probing Pocket Depth)- głębokość kieszonki podczas zgłębnikowania

PES- (Pink Esthetic Score)- współczynnik estetyki różowej

WES- (White Esthetic Score)- współczynnik estetyki białej

VAS- (Visual Analogue Scale)- analogowa skala bólu

CBCT- (Cone-Beam Computed Tomography)- komputerowa tomografia stożkowa

RVG- (Radiovisiography)- radiowizjografia

ISQ- (Implant Stability Quotient)- jednostka stabilizacji implantu

I. STRESZCZENIE:

Wstęp:

Wysoka stabilizacja pierwotna jest warunkiem *a priori*, który umożliwia wczesne obciążenie implantu i powodzenie osteointegracji. W przypadku strefy estetycznej szczęki, która obejmuje zakres od drugiego zęba przedtrzonowego prawego do drugiego zęba przedtrzonowego lewego, stosunkowo możliwie szybkie obciążenie implantu jest niezmiernie ważne, nie tylko ze względów funkcjonalnych, ale przede wszystkim z powodów estetycznych. Do zwiększenia stabilizacji pierwotnej, czyli mechanicznego zakotwienia wszczepu w łożu kostnym, która jest determinantą osteointegracji, udoskonala się geometrię implantu. Natomiast modyfikacja powierzchni implantu umożliwia przyspieszenie i zwiększenie zrostu kości z implantem. W dalszym ciągu prowadzone są intensywne prace, mające na celu opracowanie nowych typów implantów oraz metod zabiegowych, pozwalających na zwiększenie poziomu stabilizacji pierwotnej.

Celem pracy jest:

Celem pracy była porównawcza ocena stabilizacji dwóch rodzajów implantów o powierzchni modyfikowanej jonem hydroksylowym i różnej średnicy platformy w stosunku do wczesnego, funkcjonalnego ich obciążenia.

Materiał:

Materiał do badań stanowiło 40 pacjentów, bez względu na płeć, powyżej 18 roku życia z pojedynczymi brakami zębowymi w odcinku przednim szczęki. Pacjenci nie mogli mieć aktywnej choroby przyzębia i API > 25%. Do czynników wykluczających z badania zaliczono również nałogowe palenie, bruksizm, ciążę oraz karmienie piersią. Procedury sterowanej regeneracji kości nie mogły być przeprowadzane w trakcie implantacji, a okres od utraty zęba musiał wynosić minimum 3 miesiące. Pacjenci zostali poddani badaniom klinicznym i radiologicznym, na podstawie których określono minimalną szerokość wyrostka zębodołowego szczęki, kwalifikującą do badania na 6,5 mm, a wysokość bazy kostnej na 8 mm. Pacjenci zostali losowo podzieleni na 2 grupy w zależności od średnicy zastosowanego implantu:

- a) grupa 1 (G1; n = 20 pacjentów) - zostały zastosowane implanty o średnicy 3,5 mm
- b) grupa 2 (G2; n = 20 pacjentów) - zostały zastosowane implanty o średnicy 4,0 mm

Metody:

Została przeprowadzona ocena kliniczna i radiologiczna wyników leczenia. Ocena kliniczna obejmowała ocenę wskaźników: API, HKT, PPD, PES i WES. Oceniono również pomiar stabilizacji implantów z wykorzystaniem aparatu Ostell.

Ocena radiologiczna obejmowała ocenę CBCT oraz RVG, wykonaną przed, bezpośrednio po zabiegu implantacji oraz podczas wizyt kontrolnych. Obrazy CBCT i RVG zostały wykorzystane do oceny zmiany poziomu kości wyrostka wokół implantu- pomiar MBL.

Wyniki:

Podczas porównania implantów o średnicy 3,5 i 4,0 w obu przypadkach osiągnięto dobre wyniki w zakresie stabilizacji pierwotnej i wtórnej (po 4 tygodniach). Utrata kości brzeżnej wokół implantów była niska i nie stwierdzono w tej kwestii istotnej statystycznie różnicy między grupami. Dzięki osiągniętej dobrej stabilizacji pierwotnej i szybkiej osteointegracji wszczepu możliwe było wczesne, funkcjonalne obciążenie protetyczne.

Podsumowanie i wnioski:

Możliwe jest zastosowanie implantów o hydrofilowej powierzchni bez względu na ich średnicę, przy wyjściowej szerokości wyrostka zębodołowego powyżej 6,5 mm oraz w protokole wczesnego, funkcjonalnego obciążenia, osiągając wysoki efekt estetyczny.

ABSTRACT:

Introduction:

High primary stabilization is an *a priori* condition that enables early loading of the implant and the success of osseointegration. In the case of the aesthetic area of the maxilla, ranging from the second right premolar to the second left premolar, a relatively quick loading of the implant is essential, not only for functional reasons, but above all for aesthetic reasons. In order to increase the primary stabilization, i.e. the mechanical anchoring of the implant in the bone bed, which is the determinant of osseointegration, the geometry of the implant is improved. On the other hand, the modification of the implant's surface enables the acceleration and increase of connection between the bone and the implant. Intensive studies aimed at developing new types of implants and treatment methods (allowing to increase the level of primary stabilization) are still being conducted.

Aim of the study:

The aim of the study was a comparative evaluation of the stabilization for two types of implants with a surface modified with hydroxyl ion and a different diameter of the platform in relation to their early, functional loading.

Material:

The research material consisted of 40 patients, regardless of gender, above 18 years of age, with single missing teeth in the anterior part of the jaw. The patients could not have active periodontal disease and API > 25%. Compulsive smoking, bruxism, pregnancy and breastfeeding were also included in the research as excluding factors. Guided bone regeneration procedures could not be carried out during the implantation, and the period from tooth loss had to be at least 3 months. The patients were subjected to clinical and radiological examinations, on the basis of which the minimum width of the alveolar process (6.5 mm) and the bone base height (8 mm) were determined. The patients were randomly divided into 2 groups, depending on the diameter of the applied implant:

- a) group 1 (G1; n = 20 patients) - implants with a diameter of 3.5 mm were used
- b) group 2 (G2; n = 20 patients) - implants with a diameter of 4.0 mm were used

Methods:

Clinical and radiological evaluations of the treatment results was conducted. The clinical evaluation included the assessment of the following indicators: API, HKT, PPD, PES and WES. The measurement of implants' stabilization was also evaluated with the use of the Ostell apparatus.

The radiological evaluation included CBCT and RVG estimation before, immediately after the implantation procedure and during follow-up visits. CBCT and RVG images were used to evaluate the change in the level of the alveolar bone around the implant – MBL measurement.

Results:

During the comparison of implants with diameters of 3.5 and 4.0 mm, in both cases – goods results were obtained in terms of primary and secondary stabilization (after 4 weeks). The loss of marginal bone around implants was low and no statistically significant difference between the groups was found in this respect. Thanks to the achieved good primary stabilization and quick osseointegration of the implant, early functional prosthetic loading was possible.

Summary and Conclusions:

It is possible to use implants with a hydrophilic surface, regardless of their diameter, with the initial width of the alveolar process above 6.5 mm and in the early, functional loading protocol – achieving a high aesthetic effect.

1. WSTĘP

Współczesna implantologia stomatologiczna dąży do możliwie wczesnego obciążenia implantu. Ma to szczególne znaczenie w sytuacji, gdy brak ten występuje w strefie estetycznej szczęki, obejmującej zakres od drugiego zęba przedtrzonowego po stronie prawej, do drugiego zęba przedtrzonowego po stronie lewej. W przypadku leczenia implantologicznego w strefie estetycznej jako odbudowa tymczasowa, stosowane jest zazwyczaj ruchome uzupełnienie protetyczne. Może wiązać się to obniżonym komfortem użytkowania i ogranicza całościowy poziom zadowolenia z procesu terapeutycznego. W związku z tym, metody mające na celu skrócenie okresu gojenia oraz pozwalające na jak najwcześniejsze obciążenie implantu są stale poszukiwane.

Czynnikiem koniecznym do wczesnego obciążenia implantu jest osiągnięcie wysokiej stabilizacji pierwotnej, czyli mechanicznego zakotwienia się implantu w kości. Jest to również jeden z głównych warunków procesu osteointegracji, czyli stabilnego, biologicznego i funkcjonalnego połączenia implantu z kością [1–3].

Na przestrzeni lat przeprowadzono wiele badań nad czynnikami, które mogą wpływać na wzrost stabilizacji pierwotnej. Dotyczą one trzech głównych grup:

1. Ilościowa i jakościowa charakterystyka struktury kości, w którą wprowadzany jest implant [4].
2. Sposób przygotowania łoża implantu [5].
3. Makroskopowe i mikroskopowe cechy powierzchni implantu takie jak: wymiar, kształt, średnica, skok gwintu implantu oraz rodzaj powierzchni implantu [6].

W zależności od powyższych czynników czas obciążenia implantów jest różny. W przypadku szczęki, okres osteointegracji implantów, a w związku z tym możliwość ich obciążenia wynosił od 6 do 8 miesięcy. Obecnie, dzięki zastosowaniu wielu metod mechanicznych, chemicznych czy fizycznych związanych z modyfikacją powierzchni implantu okres ten został znacznie skrócony. Modyfikacje te polegały na zmianie pierwotnie gładkiej, maszynowej powierzchni wszczepu, na bardziej chropowatą, o większej powierzchni kontaktu z kością (BIC). Nadal trwają prace nad pozyskaniem powierzchni aktywnej wszczepu umożliwiającej pełne funkcjonalne obciążenie, w jak najkrótszym czasie po zabiegu implantacji.

W trakcie wgajania implantu ze zmodyfikowaną powierzchnią już między 3-4 tygodniem od wprowadzenia implantu, zachodzi proces mineralizacji i powstaje pierwotna tkanka kostna, która osiąga wartości mechaniczne umożliwiające funkcjonalne obciążenie

implantu. Należy pamiętać również o tym, iż podjęte leczenie powinno charakteryzować się długoterminową skutecznością, na którą wpływa wiele czynników.

Jednym z najważniejszych jest stan tkanek miękkich wokół implantu. Obserwacje długoterminowe pokazują, że przewidywalność przeżycia implantu u pacjentów z cienkim biotypem jest niska [7,8]. Ograniczona grubość i szerokość dziąsła zrogowaciałego jest również głównym czynnikiem zwiększającym występowanie recesji dziąsłowych wokół implantów, a także zwiększa ryzyko zapalenia błony śluzowej wokół implantu [9]. Odpowiednia wysokość i grubość dziąsła zrogowaciałego to także ważne czynniki wpływające na utrzymanie stabilnego poziomu kości brzeżnej wokół implantu i zapobiegające utracie implantu po obciążeniu [10,11,12]. Ponadto wykazano, że gruby fenotyp dziąsła warunkuje lepszy profil wylaniania uzupełnień protetycznych osadzonych na implantach [13].

Zarówno czas obciążenia, jak i rodzaj uzupełnienia protetycznego wpływają na stan tkanek miękkich wokół implantu, a co za tym idzie zadowalający efekt estetyczny. Wcześniej używane uzupełnienia cementowane, które ze względu na większe mikroszczeliny brzeżne mogą prowadzić do znacznej akumulacji biofilmu i częstszego stanu zapalnego, zastąpiono uzupełnieniami przykręcanyymi [14].

2. CEL PRACY

Celem pracy była porównawcza ocena stabilizacji dwóch rodzajów implantów o różnej średnicy platformy w stosunku do wczesnego, funkcjonalnego obciążenia implantów. Celem było również opracowanie protokołu leczenia z zastosowaniem implantów o modyfikowanej powierzchni i ich wczesnym obciążeniu funkcjonalnym.

3. AKTUALNY STAN WIEDZY NA TEMAT POWIERZCHNI IMPLANTÓW I CZASU ICH OBCIĄŻENIA

3.1. KLASYFIKACJA OBCIĄŻENIA IMPLANTÓW

W odbudowie implantoprotetycznej możemy wyróżnić 3 schematy postępowania [15]:

1. Obciążenie natychmiastowe.
2. Obciążenie wczesne.
3. Obciążenie późne.

Wszystkie 3 protokoły są obecnie stosowane w uzupełnieniu braków zębowych pojedynczych, mnogich, jak i odbudowy całego łuku zębowego.

Zastanawiając się nad wybraniem prawidłowego modelu postępowania, zaczęto badać wpływ czasu, po którym obciążano implant na występowanie i wartości MBL wokół implantu, gdyż jest to podstawowy wskaźnik prawidłowej osteointegracji, utrzymania implantu oraz braku periimplantitis. Pomiar ten określany jest na podstawie badania radiologicznego. Do tego celu można wykorzystać przekroje CBCT lub RVG. Zdjęcia rentgenowskie wewnątrzustne powinny być wykonane techniką równoległą w trybie wysokiej rozdzielczości, wykorzystując do tego celu pozycjonery kliszy bądź czujnika. W literaturze opisane są dwie główne metody pomiaru ubytku kości: analizę fraktalną oraz obliczenia oparte na pomiarach w milimetrach przeprowadzonych na podstawie badania radiologicznego. W przedstawionych publikacjach, w celu obliczenia MBL, wybrano dwa zdjęcia każdego regionu, w dniu implantacji oraz po 12 miesiącach. Średnica implantów została wykorzystana jako punkt odniesienia do kalibracji. Pomiary dotyczyły odległości pomiędzy platformą implantu a pierwszym radiologicznym kontaktem kość-implant po stronie dystalnej i mezialnej.

Obciążenie natychmiastowe

Istnieje wiele definicji obciążenia natychmiastowego oraz kryterium czasowego w tym zakresie. Według Ostmana [16] obciążenie natychmiastowe, inaczej bezpośrednie, określa jako osadzenie korony protetycznej do 24 godzin od implantacji. Według innych autorów [17] maksymalny czas osadzenia odbudowy na implancie określony jest na 48 godzin, a według Esposito i wsp. jest to nawet 7 dni od implantacji [18].

Rozbieżności występują również odnośnie kontaktów okluzyjnych dostarczonej korony bądź innego uzupełnienia protetycznego. Niektórzy autorzy uważają, iż taka praca protetyczna może być w dyskluzji, inni zaś, że pełne określenie "obciążenie natychmiastowe" dotyczy tylko odbudowy protetycznej biorącej udział w pełnej okluzji, zarówno w ruchach centrycznych jak i ekscentrycznych [19]. Zastosowanie leczenia w postaci implantacji z obciążeniem natychmiastowym niesie za sobą wiele korzyści. Według badania Esposito i wsp. [20], w którym porównano natychmiastowe, funkcjonalne obciążenie implantu do odbudowy tymczasowej wyłączanej ze zgryzu, postępowanie takie przede wszystkim skraca czas leczenia i liczbę wizyt, co zapewnia wysoką satysfakcję pacjenta.

Pewną zgodność można zaobserwować w kryteriach umożliwiających zastosowanie obciążenia natychmiastowego. Najważniejszym kryterium jest osiągnięcie prawidłowej stabilizacji pierwotnej przez implant. Na podstawie metaanalizy danych przeprowadzonej przez Esposito i wsp. [18] wartość ta została określona jako powyżej 35 Ncm osiągniętej na kluczu dynamometrycznym podczas jego wszczepiania we wcześniej wytworzonym łożu kostnym.

Osiągnięcie wysokiego poziomu stabilizacji pierwotnej, umożliwia zastosowanie protokołu natychmiastowego obciążenia. Według Błaszczyszyna i wsp. [21] podstawowymi czynnikami wpływającymi na wartość stabilizacji pierwotnej są: odpowiedni kształt i powierzchnia implantu, odpowiednia jakość kości oraz prawidłowa preparacja łoża kostnego. Do odpowiedniego przygotowania implantodołu można wykorzystać nie tylko dedykowane wiertła implantologiczne, ale również narzędzia ultradźwiękowe.

Szybka odbudowa braku zębowego prowadzi do wzrostu komfortu pacjenta oraz niweluje niekorzystne aspekty psychologiczne z powodu utraty zęba [22]. Unikamy również konieczności drugiego zabiegu chirurgicznego w postaci odsłonięcia implantu i wprowadzenia śruby gojącej. Dzięki natychmiastowemu wprowadzeniu korony, utrzymujemy odpowiedni kontur tkanek (przede wszystkim brodawki dziąsłowej), co gwarantuje wysoki efekt estetyczny [23].

Czynnikami ryzyka podczas obciążenia natychmiastowego są znaczne dysproporcje łuków zębowych w wymiarze strzałkowym i pionowym, co wiąże się z nieprawidłowym zgryzem. Należy do nich również bruksizm, wcześniejsza utrata implantu w wywiadzie oraz wszystkie pozostałe ogólne przeciwwskazania do implantacji konwencjonalnej.

Obciążenie wczesne

Jako obciążenie wczesne określa się odbudowę implantoprotetyczną przeprowadzoną do 2-3 miesięcy od implantacji, jednakże średni czas to 3-6 tygodni. Istotnym wydaje się podkreślenie faktu, iż okres ten jest krytyczny ze względu na spadek stabilizacji pierwotnej oraz jeszcze niepełną stabilizację wtórną, mimo powstania pierwotnej tkanki kostnej wokół implantu [16,17,18]. Trzeba również zaznaczyć, że implanty z odpowiednio zmodyfikowaną powierzchnią np. w wyniku trawienia kwasem, stabilizację wtórną osiągają znacznie szybciej niż implanty konwencjonalne [24].

Obciążenie wczesne implantów, podobnie jak natychmiastowe, pociąga za sobą wiele aspektów pozytywnych m.in. mniej interwencji chirurgicznych, zmniejszenie utraty tkanek miękkich i twardych, czy też skrócenie całkowitego czasu leczenia, co umożliwia szybsze podjęcie podstawowych funkcji takich jak jedzenie, żucie i prawidłowa artykulacja [25].

Obciążenie późne

Stwierdzenie to jest stosowane w przypadkach, gdy konstrukcję protetyczną mocuje się w kolejnym etapie, po konwencjonalnym okresie gojenia, który wynosi minimum 3-6 miesięcy [17,26]. Jest to postępowanie 3 etapowe. W schemacie tym, w pierwszym etapie, implant po

wprowadzeniu jest uspiiony i zachodzi proces osteointegracji. Po upływie 3-6 miesięcy następuje etap drugi, czyli odsłonięcie implantu wraz z wprowadzeniem śruby gojącej. Etapem trzecim jest wykonanie korony protetycznej.

Jest to najczęściej stosowany protokół postępowania. Jako zaletę należy wymienić przede wszystkim zmniejszone ryzyko utraty implantu po obciążeniu [18]. Dedykowany jest przypadkom, w którym nie osiągnięto stabilizacji pierwotnej powyżej 20 Ncm, czy też w sytuacjach implantacji z jednoczasową rozległą augmentacją, bądź gdy pacjent nie jest przekonany do obciążenia natychmiastowego i powiązanego z nim ewentualnego ryzyka.

3.2 WPLYW POWIERZCHNI IMPLANTU NA CZAS OBCIĄŻENIA

Modyfikacja mikropowierzchni implantu zwiększa powierzchnię jego kontaktu z kością, jak i wpływa na morfologię komórek, tak aby przyspieszyć proces osteointegracji [27,28]. W tym miejscu należy jednak podkreślić, iż przy zbyt dużej chropowatości dochodzi do mikroprzecieku, czyli uwalnianiu związków chemicznych do środowiska zewnętrznego [29,30]. Niemniej powierzchnia gładka nie daje optymalnych warunków do zaistnienia procesów osteogenezy bezpośrednio na powierzchni implantu [31].

Jak wykazano, odpowiednia modyfikacja struktury implantu, np. poprzez piaskowanie ziarnami m.in. tlenku glinu, tytanu, fotofunkcjonalizację, napyłania plazmą, zanurzenie w specjalnym roztworze, bądź w wyniku trawienia kwasem, zwiększa prawdopodobieństwo osiągnięcia stabilizacji pierwotnej poprzez implant, na poziomie umożliwiającym jego natychmiastowe lub wczesne obciążenie [32].

W przeprowadzonym badaniu został wykorzystany implant, które przed wprowadzeniem w łożo kostne, zanurzany jest w specjalnym roztworze zawierającym aktywne jony wodorotlenowe (OH⁻). Ich celem jest zwiększenie energii powierzchniowej implantu prowadząc w ten sposób do większej hydrofilności i szybszej absorpcji białek na jego powierzchni. Wspomagając w ten sposób wcześniejsze przyleganie kości i zapewniając większą stabilność implantu podczas pierwszych krytycznych tygodni osteointegracji [33, 34].

4. MATERIAŁ I METODY

Materiał stanowiący podstawę niniejszej rozprawy doktorskiej został podzielony na dwie części. Część pierwsza opisuje badania własne, natomiast część druga skupia się na analizie dostępnych publikacji opisujących wpływ czasu obciążenia implantów na zanik kości brzeżnej.

4.1. Zastosowanie implantów o modyfikowanej powierzchni w protokole wczesnego funkcjonalnego ich obciążenia.

Materiał do badań stanowiło 40 pacjentów, zakwalifikowanych do badania bez względu na płeć, będących powyżej 18 roku życia oraz mających pojedynczy brak zębowy w odcinku przednim szczęki. Pacjenci nie mogli mieć aktywnej choroby przyzębia i API > 25%. Do czynników wykluczających z badania zaliczono nałogowe palenie, bruksizm, ciążę oraz karmienie piersią. Procedury sterowanej regeneracji kości nie mogły być przeprowadzane w trakcie implantacji, a okres od utraty zęba musiał wynosić minimum 3 miesiące. Pacjenci zostali poddani badaniom klinicznym i radiologicznym, na podstawie których określono minimalną szerokość wyrostka zębodołowego szczęki, kwalifikującą do badania, na 6,5 mm, a wysokość bazy kostnej na 8 mm. Pacjenci zostali losowo podzieleni na 2 grupy w zależności od średnicy zastosowanego implantu

- a) grupa 1 (G1; n= 20 pacjentów) - zostały zastosowane implanty o średnicy 3,5 mm
- b) grupa 2 (G2; n= 20 pacjentów) - zostały zastosowane implanty o średnicy 4,0 mm

Badanie zostało przeprowadzone w pełnej zgodności z Deklaracją Helsińską. Pacjenci wyrazili dwie świadome pisemne zgody: pierwszą, ogólną zgodę na leczenie implantologiczne oraz drugą zgodę obejmującą udział w badaniu.

Została przeprowadzona ocena kliniczna i radiologiczna wyników leczenia. Ocena kliniczna obejmowała ocenę wskaźników: API, HKT, PPD, PES i WES, ocenę biotypu dziąsła i brodawek dziąsłowych. Oceniono również pomiar stabilizacji implantów z wykorzystaniem aparatu Ostell.

Ocena radiologiczna obejmowała ocenę CBCT oraz RVG, wykonywaną bezpośrednio po zabiegu implantacji oraz podczas wizyt kontrolnych, celem określenia stopnia MBL.

Szczegółowy opis materiału i metod dotyczących tego zagadnienia zawarto w załączonych publikacjach:

1. Krawiec M, Hadzik J, Dominiak M, Grzebieluch W, Błaszczyszyn A, Kubasiewicz-Ross P. Early loading of titanium dental implants with hydroxyl ion modified surface: a 12-month prospective clinical trial. *Applied Sciences-Basel*. 2021;11(7): art. doi:10.3390/app11072958.
2. Krawiec M, Hadzik J, Olchowy C, Dominiak M, Kubasiewicz-Ross P. Aesthetic outcomes of early occlusal loaded SLA dental implants with hydroxyl ion modified surface- a 12 months prospective study. *Materials*. 2021;14(21): art. doi:10.3390/ma14216353.

4.2. Wpływ czasu obciążenia implantu na zanik kości brzeżnej- przegląd piśmiennictwa.

Przeszukiwanie literatury przeprowadzono w internetowej bazie danych PubMed/MEDLINE. Pod uwagę brane były wyłącznie publikacje w języku angielskim, badania na ludziach z co najmniej 12-miesięcznym okresem obserwacji oraz badania opublikowane między styczniem 2002 a czerwcem 2021 roku. Uwzględniono jedynie publikacje opublikowane jako pełne teksty, abstrakty i plakaty zostały wykluczone. W wyniku przeszukiwania znaleziono łącznie 1366 publikacji z czego 10 uwzględniono w analizie jakościowej.

Stosując strategię badawczą zgodnie z kryteriami PICOS (P- Population, I- Intervention, C- Comparison, O- Outcome, S- Study design) została przeprowadzona analiza zebranych publikacji, w których przedstawiono wpływ czasu obciążenia na wartość i stopień MBL.

Szczegółowy opis materiału oraz metod dotyczący tego zagadnienia zawarto w załączonej publikacji:

1. Krawiec M, Olchowy C, Kubasiewicz-Ross P, Hadzik J, Dominiak M. Role of implant loading time in the prevention of marginal bone loss after implant-supported restorations: A targeted review [published online as ahead of print on May 24, 2022]. *Dent Med Probl*. doi:10.17219/dmp/150111

5. WYNIKI

5.1. Zastosowanie implantów o modyfikowanej powierzchni w protokole wczesnego funkcjonalnego ich obciążenia.

Spośród 40 implantów umieszczonych w fazie chirurgicznej, każdy implant osiągnął osteointegrację, a co za tym idzie wysoki poziom stabilności wtórnej i mógł zostać obciążony. Wszystkie implanty z powodzeniem przetrwały 12-miesięczny okres obserwacji.

Nie było statystycznie istotnych różnic w zaniku kości brzeżnej między implantami o średnicy 3,5 mm (0,26 mm ($\pm 0,31$)) a 4,0 mm (0,14 mm ($\pm 0,24$)).

Średnie wartości PPD w grupach 3,5 i 4,0 były porównywalne: 2,17 mm ($\pm 0,53$) vs 2,04 mm ($\pm 0,37$), bez statystycznie istotnych różnic między nimi. Średnica implantu nie miała wpływu również na pomiary HKT.

Dla wszystkich implantów osiągnięto dobre wyniki estetyczne. Nie stwierdzono różnic w estetyce różowej- PES (9,5) zarówno dla grup 3,5 mm, jak i 4,0 mm. Nieco lepsze wyniki uzyskano dla implantów o średnicy 3,5 mm w estetyce białej- WES- 9,78 vs 9,72, ale nie były one istotne statystycznie.

Po zabiegu nie stwierdzono również istotnych statystycznie różnic w odczuwaniu bólu dla grup 3,5 i 4,0.

Poziom stabilizacji implantu spadł w ciągu czterech tygodni obserwacji. Szersza średnica implantu zapewniała ogólnie wyższy poziom stabilizacji pierwotnej i wtórnej, ale bez istotnych różnic. W grupie 1 odpowiednio 70,84 ISQ ($\pm 3,39$) i 69,50 ISQ ($\pm 3,31$)), a w grupie drugiej 72,30 ISQ ($\pm 4,56$) i 70,39 ISQ ($\pm 3,29$). Zaobserwowano istotne dodatnie korelacje dla zmiennych Ostell 0 (stabilizacja pierwotna) i Ostell 1 (stabilizacja wtórna), co oznacza, że wyższym wartościom stabilizacji pierwotnej towarzyszyły wyższe wartości stabilizacji wtórnej.

Ponadto stwierdzono istotną statystycznie korelację między starszym wiekiem pacjentów, a niższymi wartościami stabilności pierwotnej i wtórnej w grupie pierwszej i drugiej.

5.2. Wpływ czasu obciążenia implantu na zanik kości brzeżnej- przegląd piśmiennictwa.

Ogólnie 10 badań spełniło kryteria włączenia i podało wartości MBL wraz z definicjami protokołów obciążenia. Po 12 miesiącach wartości MBL wahały się od 0,17 mm do 1,86 mm

u pacjentów poddanych protokołowi natychmiastowego obciążenia, od 0,14 mm do 1,22 mm
u pacjentów poddanych protokołowi wczesnego obciążenia oraz od 0,44 mm do 0,91 mm
u pacjentów poddanych protokołowi obciążenia odroczonego.

Wyniki omówiono szczegółowo w załączonych publikacjach stanowiących podstawę niniejszej rozprawy doktorskiej.

6. PODSUMOWANIE I WNIOSKI

1. Implanty o hydrofilowej powierzchni mogą być stosowane w protokole wczesnego funkcjonalnego obciążenia.
2. Wyższe wartości stabilizacji pierwotnej wpływają pozytywnie na wartości stabilizacji mierzonej cztery tygodnie po implantacji.
3. Wraz ze wzrostem wieku pacjenta zmniejszają się wartości stabilizacji pierwotnej i wtórnej
4. Osiągnięte wartości MBL są porównywalne z wynikami osiąganymi przez innych autorów
5. Zarówno implanty wąskie o średnicy 3,5 mm jak i 4,0 mm mogą być stosowane w protokole wczesnego obciążenia funkcjonalnego z dobrymi efektami estetycznymi.
6. Proponowany protokół postępowania w postaci wczesnego funkcjonalnego obciążenia implantów jest przewidywalny i można wdrożyć go do praktyki klinicznej stosując ograniczenia zawarte w kryteriach wykluczających z badania.

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II. PRACE STANOWIĄCE PODSTAWĘ ROZPRAWY DOKTORSKIEJ

1. **Maciej Krawiec**, Jakub Hadzik, Marzena Dominiak, Wojciech Grzebieluch, Artur Błaszczyszyn, Paweł Kubasiewicz-Ross. Early loading of titanium dental implants with hydroxyl ion modified surface: a 12-month prospective clinical trial. *Applied Sciences-Basel*. 2021;11(7):art. doi:10.3390/app11072958.
2. **Maciej Krawiec**, Jakub Hadzik, Cyprian Olchowcy, Marzena Dominiak, Paweł Kubasiewicz-Ross. Aesthetic outcomes of early occlusal loaded SLA dental implants with hydroxyl ion modified surface - a 12 months prospective study. *Materials*. 2021;14(21):art. doi:10.3390/ma14216353.
3. **Maciej Krawiec**, Marzena Dominiak, Jakub Hadzik, Paweł Kubasiewicz- Ross, Cyprian Olchowcy. Role of implant loading time in the prevention of marginal bone loss after implant-supported restorations: A targeted review [published online as ahead of print on May 24, 2022]. *Dent Med Probl*. doi:10.17219/dmp/150111

Article

Early Loading of Titanium Dental Implants with Hydroxyl Ion Modified Surface: A 12-Month Prospective Clinical Trial

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Featured Application: The following paper presents the issue of early loading of dental implants. Nowadays, the most frequently used prosthetic protocol is loading the implant within 12 weeks. It is believed that the recently introduced nano-scale modification of the implant's surface will allow for faster final loading. Faster final loading reduces the overall treatment time which is even more crucial in the case of aesthetic zone rehabilitation.

Abstract: (1) Background: implant surface topology and active hydrophilic ions could have some benefit on implant osteointegration and stability; (2) methods: 40 adult patients, suffering from a single missing tooth in the aesthetic zone, were enrolled in the study. Each patient had a single titanium implant (Thommen SPI[®]lement) inserted. The implant surface was obtained through conditioning using the Apliquiq system. Patients were divided into two equal groups depending on the implant's diameter (3.5 and 4.0 mm). Each implant was loaded within four weeks. Stability levels, using the Ostell device, were checked immediately after implant placement and in four weeks; additionally, marginal bone loss (MBL) was calculated based on 12 months; (3) results: all implants survived the study. The average primary stability achieved for both groups was initially 71.59 ISQ (± 4.04) and declined to 69.94 ISQ (± 3.29) in four weeks. The average MBL was 0.2 mm (± 0.88). There were no statistically important differences between groups. There was a positive correlation between the patient's age and implant stability quotient (ISQ) values; (4) conclusions: hydrophilic surface implants can be used in a protocol for early functional occlusal loading. Higher values of primary stability positively influence the values of secondary stability, and the age of the patient affects the values of implant stability.

Keywords: dental implant; primary stability; secondary stability; marginal bone loss; early loading



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1. Introduction

In the case of implant treatment, which involves the aesthetic zone of the maxilla, immediate or early loading of an implant is extremely important, not only for functionality, but primarily for aesthetic reasons. For decades, high primary stability has been the key factor in determining the early loading of an implant and the success of a treatment [1,2].

Osteointegration has been defined as a direct and functional connection between the bone and an artificial implant [2]. Primary stability is the grade of engagement of an implant in the bone structure immediately after insertion. It is one of the main conditions for the osteointegration process [1–3]. The factors that influence the values of primary stability can be divided into three main groups. The first one is the quantitative and qualitative characteristics of the bone structure into which the implant is inserted [4]. Another factor

is the method of implant bed preparation [5]. The final factor affecting primary stability are the characteristics of an implant, which include both the macroscopic and microscopic features of the implant surface [6]. The macroscopic features of an implant relate to aspects such as the dimensions, shape, diameter and thread pitch of the implant. The microscopic features are the overall characteristics of the surface, primarily including the grade of the roughness of the surface [1–3,6].

In the context of osteointegration, much attention has been paid in recent years to the physical and chemical aspects of dental implant surfaces. These include electrochemical potential, surface wettability, thickness of the titanium dioxide (TiO₂) layer, ion adhesion, active peptides, growth factors, and antibiotics. Currently, work is still underway to develop a type of surface that would allow for even faster loading of an implant even when primary stability is low [7–9]. One such potential method is the chemical modification of the surface using hydroxyl ion. With such a modification, the titanium surface of an implant has a negative electrochemical potential. The negative potential determines the improvement of the osteointegration process at all stages, starting from better stability of blood clot and adhesion of Ca⁺⁺ ions in the first hours after the loading of a dental implant, through to a better adhesion of proteins (fibronectin, osteocalcin) and the cells that determine the process of osteointegration (mesenchymal stem cells (MSC)) in the later stages of the process [10,11].

In the case of implant treatment within the aesthetic zone, a temporary restoration, usually a removable one, is needed. It causes many difficulties for the patient. Therefore, the methods for shortening the healing period and loading an implant as early as possible are constantly being sought after. The first reports claiming a high rate of success concerning early loading of an implant date back to the 1990s and refer to the Branemark implant system [9,10].

For decades, implant loading after six weeks was considered an early loading. However, it seems that the key period for the process of osteointegration and secondary stability is in the third and fourth week. During that time, the process of mineralization of the primary osseous tissue takes place, and thus, the bone tissue that surrounds an implant achieves the mechanical values that enable loading. Therefore, it seems reasonable to load an implant even faster, i.e., after 3–4 weeks of healing [9–15].

The main objective of the study was to assess the marginal bone loss and stability of the early loaded Thommen Incell[®]SPI implants using the single non-splinted screw-retained final chairside-prepared prosthetic restoration. The secondary objective was to evaluate the influence of an implant's diameter on the mentioned parameters.

2. Materials and Methods

2.1. Inclusion and Exclusion Criteria

In this study, 40 patients aged over 18, partially edentulous within the aesthetic zone, were enrolled. The patients could not have any active periodontal disease or an approximal plaque index (API) > 25%. The patients were subjected to clinical and radiological examinations. The minimum alveolar ridge dimension in the lingual–buccal aspect was 6.5–7 mm in the region of interest, so the implant could be placed in the native bone. Furthermore, the bone density in the region of the implant insertion had to be D2 or D3 according to Misch et al. [16]. Patients were randomly divided into 2 separate groups depending on the implant diameter used (3.5 and 4.0 mm).

- (a) group 1 (G2; n = 20 patients)—3.5 mm diameter implants were used
- (b) group 2 (G3; n = 20 patients)—4.0 mm diameter implants were used

The procedures of the guided bone regeneration were not performed neither before nor during the implant placement. Furthermore, at least 3 months for the healing period after extraction were established.

Exclusion criteria were:

1. systemic or local diseases that could compromise healing or osteointegration,

2. heavy smokers,
3. patients with bruxism,
4. pregnancy,
5. breastfeeding.

2.2. Protocol of the Experiment

The schedule of visits included:

1. consultation visit: qualification of the patient for the surgery, clinical and radiological examination CBCT (cone-beam computed tomography) (Galileos[®]D3437, Sirona Dental, Erlangen, Germany), API assessment;
2. implantation: intraoperative and postoperative RVG (radiovisiography) (Planmeca OY, Helsinki, Finland), torque values, primary stability assessment using Ostell ISQ (Ostell; Integration Diagnostics, Gothenburg, Sweden);
3. 4 weeks after the implantation: assessment of stability with the use of Ostell ISQ, intraoral scan, placement of prosthetic, RVG;
4. 12 months after the surgery: clinical and radiological assessment (RVG and CBCT).

The research was performed in accordance with the conditions of declaration of Helsinki and with the approval of the Local Ethical Committee (229/2019). The personal data protection procedures (GDPR) were complied with. The patients signed two written consents: first, a general consent for the implant treatment, and second, consent for participation in the study.

2.3. Implants

The cylindrical dental implants, Thommen Innicell[®]SPI Element MC Innicel (Thommen Medical AG, Grenchen, Switzerland) were used for the surgery. The superhydrophilic implant surface was obtained through NaOH conditioning using the Apliquiq system (Thommen Medical AG, Grenchen, Switzerland). The length of the inserted implants ranged from 8 mm to 11 mm and depended on the height of the bone base, while the diameter of the implant was determined by the width of the alveolar processes.

2.4. Surgical Phase

The implant surgery was performed with antibiotic cover, one-shot therapy: 1 dose of clindamycin 600 mg (MIP Pharma, Gdansk, Poland). Infiltration anesthesia was applied using Septanest 1:100,000 (SEPTODONT 58, Saint Maur des Fossés, France) with the Wand STA device (Milestone Scientific, Inc., Roseland, NJ, USA). A diamond drill was used for deepithelialization and a blade (no. 15C) was used for an H-shaped papilla-preservation incision, shifted palatally. Next, each implant was inserted at bone level, according to the procedure provided by the manufacturer. Subsequently, the primary stability was assessed using Ostell ISQ. The measurements were performed three times in the mesiodistal, buccal and palatal, as well as periapical direction measurements with the application of Ostel smartpeg for the Thommen implants. The smallest value was considered to be the cut-off point. Open healing was used with a standard healing screw. The partially deepithelialized flap was repositioned and stabilized with 0–5 simple interrupted sutures (Seralene[®], Serag Wiessner, Naila, Germany). At the end of the surgery, a RVG image was taken to assess the correctness of the inserted implant (Figure 1). The X-ray tubehead was aimed at right angles (vertically and horizontally) to both the implant and the sensor. A paralleling device was used for this purpose. The surgeries were performed by three members of the team: M.K., J.H. and A.B. Postoperative recommendations included analgesic and anti-inflammatory treatment with Nimesil (Laboratories Menarini SA, Barcelona, Spain) at 200 mg/per day, and rinsing the oral cavity with Eludril Classic (Pierre Fabre S.A, Paris, France) 3 times a day.



Figure 1. Implant with the healing abutment placed in bicuspid region and left for open healing.

2.5. Prosthetic Phase

The prosthetic restoration stage started 4 weeks after the implant placement surgery and was prepared in the chairside laboratory by W.G. Patients with no signs of inflammation in the direct vicinity of the implant and with an ISQ (implant's stability quotient) value of 65 or greater were allowed to participate in the prosthetic protocol. The measurements using the aforementioned device were performed three times in the mesiodistal, buccal and palatal, as well as periapical direction, and the smallest value was considered the cut-off point. Screw-retained implant crowns made of lithium disilicate glass-ceramics, IPS e max CAD LT (Ivoclar Vivadent AG, Schaan, Liechtenstein), were used as the prosthetic restoration materials. After the removal of the healing abutment, the implant bed was cleaned. The scans were taken with an intraoral scanner Sirona Cerec AC Bluecam (DentsplySirona, York, PA, USA) (Figure 2). Subsequently, the crown internal surface was etched and then fixed using Multilink Hybrid Abutment cement (Ivoclar Vivadent AG, Schaan, Liechtenstein) on the previously sandblasted titanium base (TiBase) for Sirona Cerec (DentsplySirona, York, PA, USA). The crown was then screwed onto the implant with a force of 25 Ncm. The occluding relations were controlled using articulating paper (Bausch®, Cologne, Germany) with a thickness of 200, 80, and 8 μm . The hole was filled in with Gradia composite (GC Corporation, Tokyo, Japan) and an RVG image was taken (Figure 3). The patients were instructed on proper hygiene around the dental implant.



Figure 2. Implant with scanbody prepared for intraoral scan.



Figure 3. Implant loaded with the screw-retained crown.

2.6. Assessment of Implant's Stability

Values of the implant's stability quotient (ISQ) were obtained immediately after implant placement (primary stability) and after 4 weeks (secondary stability). For every series of resonance frequency analysis (RFA) measurements, the ISQ values were recorded using an Osstell device in three different directions: vertical, buccal and palatal. A transducer (Smartpegs) was attached to the implant, and ISQs ranging from 1 to 100 were recorded. The Osstells were brought into very close contact with the Smartpegs without touching them, until an audible signal confirmed that the measurement had been taken.

2.7. MBL (Marginal Bone Loss) Assessment Using the Radiological Examination

Before surgery and during the 12-month follow-up, CBCT was performed to assess the marginal bone loss (MBL). The MBL was calculated as follows: first, dimensions were calibrated by the known parameters of the implant diameter and length. Starting from the implant shoulder, distances were measured to the mesial and distal points of the bone to implant contact, parallel to the implant axis. All measurements were taken by P.K.R, a member of the research group who was not involved directly in the preparation of the implant.

2.8. Statistical Analyses

To answer the research questions, statistical analyses were performed using the IBM SPSS Statistics 25 software (IBM, New York, USA). The software was used to analyze the basic descriptive statistics together with the Shapiro–Wilk test. To examine the differences between two or more groups, a non-parametric equivalent of variance analysis, the Kruskal–Wallis test, was used. Dunn's test with the Bonferroni correction was chosen for post hoc comparisons. The relationships between continuous variables were examined by calculating Pearson's linear correlation coefficient. The value of $\alpha = 0.05$ was assumed as the significance level.

To check the distribution of continuous variables and to study their compliance with a normal distribution, basic descriptive statistics were used, and the Shapiro–Wilk test of normal distribution was performed. For nominal variables, the frequency and the percentage of individual values in the entire observation pool were calculated. The results were presented separately for the three groups. In the first group, all observations were taken into consideration while the second group included only those observations for which an implant diameter = 3.5 mm, and in the third group the implant diameter = 4.0 mm.

3. Results

3.1. General Data

The average age of all patients (groups one and two combined) was 41.55 (± 8.85). Group two consisted of younger patients (40.15 ± 5.38) and group one included generally older patients (42.99 ± 11.30).

Out of 40 implants placed in the surgical phase, each implant achieved a high level of primary stability with an ISQ value of 65 or greater. Subsequently, all patients were admitted to the prosthetic phase. Furthermore, all implants successfully survived the 12-month follow-up period.

3.2. Results of Primary and Secondary Stability

The level of stability dropped within a period of four weeks of observation. The average primary stability (Ostell 0) achieved for a total of 40 implants was 71.59 ISQ (± 4.04) and declined to 69.94 ISQ (± 3.29) at the prosthetic phase (Ostell 1). The wider diameter of the implant provided a generally higher stability level, as the average results of the primary (72.30 ISQ (± 4.56)) and secondary (70.39 ISQ (± 3.29)) stability was higher for group two than for group one (70.84 ISQ (± 3.39) and 69.50 ISQ (± 3.31)), respectively (Table 1 and Figure 4).

Table 1. Descriptive statistics and the normality test to determine distribution for selected variables.

Group	Variable	M	Me	SD	Sk.	Kurt.	Min.	Max.	W	P
Group 1 and 2 combined	Age	41.55	40.00	8.85	1.30	2.49	26.00	68.00	0.87	0.001
	Ostell 0	71.59	71.00	4.04	0.30	0.73	62.00	82.00	0.97	0.506
	Ostell 1	69.94	70.00	3.29	0.52	0.02	65.00	78.00	0.96	0.181
	MBL	0.20	0.00	0.88	1.27	0.81	0.00	1.00	0.75	<0.001
1	Age	42.95	38.00	11.30	1.06	0.71	26.00	68.00	0.83	0.006
	Ostell 0	70.84	70.00	3.39	0.24	0.16	65.00	78.00	0.96	0.679
	Ostell 1	69.50	69.50	3.31	0.69	0.08	65.00	77.00	0.95	0.477
	MBL	0.26	0.20	0.31	1.17	0.75	0.00	1.00	0.82	0.003
2	Age	40.15	41.00	5.38	-0.25	-0.66	31.00	50.00	0.96	0.673
	Ostell 0	72.30	72.00	4.56	0.11	0.86	62.00	82.00	0.95	0.482
	Ostell 1	70.39	70.00	3.29	0.44	0.54	65.00	78.00	0.95	0.492
	MBL	0.14	0.00	0.24	1.33	0.07	0.00	0.65	0.62	<0.001

M—arithmetic mean, Me—median, SD—standard deviation, Sk.—skewness, Kurt.—kurtosis, Min.—minimum, Max.—maximum, W—Shapiro–Wilk test statistic. The statistically important differences are highlighted in red.

3.3. Results of Marginal Bone Loss

The MBL in the 12-month follow-up period was higher in group one (0.26 mm (± 0.31)) when compared to group two (0.14 mm (± 0.24)) (Table 1 and Figure 5). The averaged MBL for all of the patients (groups one and two) was 0.2 mm (± 0.88).

3.4. Results of Statistical Analyses

Positive significant correlations were observed for Ostell 0 and Ostell 1 variables, which means that the higher values of the primary stability were accompanied by higher values of stability measured four weeks after implantation. That correlation was evident in both groups. Furthermore, the statistically significant correlation between the older age of the patient and lower primary and secondary stability values in groups one and two was found. A negative statistical correlation for all implants between Ostell 1 and Ostell 0, as well as between MBL and Ostell 0/Ostell 1 values was found (Tables 2–5). Additionally, no significant differences between groups with 3.5 and 4.0 mm implants were observed regarding primary (Ostell 0) and secondary (Ostell 1) stability, as well as MBL values (Table 6).

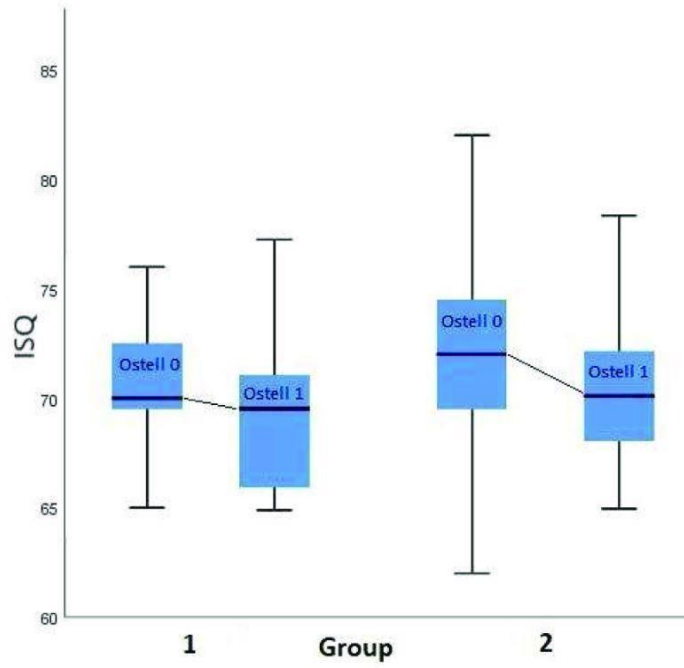


Figure 4. Results of the primary (Ostell 0) and secondary (Ostell 1) stability in both groups.

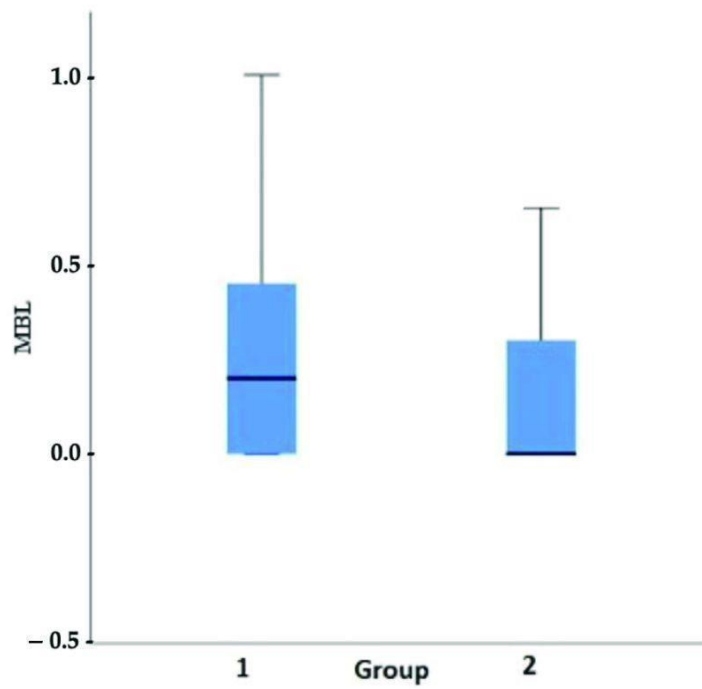


Figure 5. Results of marginal bone loss in both groups.

Table 2. Linear correlation coefficient for groups one and two and their significance for the selected continuous variables.

Variable	Coefficient	Age	Ostell 0	Ostell 1	MBL
Age	Pearson's <i>r</i>	1	−0.28	0.22	−0.06
	<i>P</i>	<0.001	0.082	0.201	0.735
Ostell 0	Pearson's <i>r</i>	−0.28	1	0.58	−0.11
	<i>P</i>	0.082	<0.001	<0.001	0.531
Ostell 1	Pearson's <i>r</i>	0.22	0.58	1	−0.06
	<i>P</i>	0.264	0.447	0.536	0.623
MBL	Pearson's <i>r</i>	−0.06	−0.11	−0.06	1
	<i>P</i>	0.735	0.531	0.736	<0.001

Table 3. Linear correlation coefficients for group one and their significance for the selected continuous variables. The statistically important differences are highlighted in red.

Variable	Coefficient	Age	Ostell 0	Ostell 1	MBL
Age	Pearson's <i>r</i>	1	−0.24	0.47	−0.37
	<i>P</i>	<0.001	0.325	0.047	0.128
Ostell 0	Pearson's <i>r</i>	−0.24	1	0.42	0.09
	<i>P</i>	0.325	<0.001	0.084	0.730
Ostell 1	Pearson's <i>r</i>	0.47	0.42	1	−0.05
	<i>P</i>	0.584	0.222	0.430	0.874
MBL	Pearson's <i>r</i>	−0.37	0.09	−0.05	1
	<i>P</i>	0.128	0.730	0.837	<0.001

Table 4. Linear correlation coefficients for group two and their significance for the selected continuous variables.

Variable	Coefficient	Age	Ostell 0	Ostell 1	MBL
Age	Pearson's <i>r</i>	1	−0.37	−0.11	0.47
	<i>P</i>	<0.001	0.105	0.663	0.047
Ostell 0	Pearson's <i>r</i>	−0.37	1	0.69	−0.20
	<i>P</i>	0.105	<0.001	0.001	0.422
Ostell 1	Pearson's <i>r</i>	−0.11	0.69	1	0.00
	<i>P</i>	0.055	0.320	0.733	0.814
MBL	Pearson's <i>r</i>	0.47	−0.20	0.00	1
	<i>P</i>	0.047	0.422	0.992	<0.001

Table 5. Kruskal–Wallis test results for Ostell and MBL variables.

Variable	d1 (<i>n</i> = 3)			d2 (<i>n</i> = 28) *			d3 (<i>n</i> = 5) †			<i>H</i>	<i>p</i>	η^2
	Average rank	<i>Me</i>	<i>IQR</i>	Average rank	<i>Me</i>	<i>IQR</i>	Average rank	<i>Me</i>	<i>IQR</i>			
Ostell 0	32.17	75.00	—	21.63	72.00	4.00	5.75	67.00	3.00	13.58	0.001	0.35
Ostell 1	32.50	75.00	—	18.98	70.00	4.00	7.40	68.00	3.00	11.16	0.004	0.28
MBL	17.00	0.00	—	19.56	0.00	0.45	15.20	0.00	0.28	1.66	0.646	−0.01

Note: *—for MBL *n* = 30, †—for MBL *n* = 6.**Table 6.** The Student's *t*-test results for a grouping variable (diameter) and selected dependent variables.

Variable	3.5 diameter		4.0 diameter		<i>T</i>	<i>P</i>	Cohen's <i>d</i>
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>			
MBL	0.26	0.31	0.14	0.24	1.30	0.203	0.43
Ostell 0	70.84	3.39	72.30	4.56	−1.13	0.266	−0.36
Ostell 1	69.50	3.31	70.39	3.29	−0.81	0.425	−0.27
Age	42.95	11.30	40.15	5.38	1.00	0.326	0.32

4. Discussion

The values for implant stability can be affected by many factors, though not in the same proportions. Sim and Lang investigated the influence of bone density structure and implant length on stability levels, and reported that the length of the implant influences the implant stability only at the time of the surgery and has lesser impact on further stages of osteointegration. Conversely, bone density seems to influence the stability level in a greater way and on all stages of osteointegration [17]. Subsequently, to standardize the sample population, we selected homogenous bone sites of the frontal aspect of the maxilla as a region of interest.

In our study, a decrease in the stability level in the four weeks following the implant insertion was observed (Figure 4). These results are in accordance with other studies and suggest the existence of bone resorption in direct contact with the implant surface. This behavior is attributed to the time dependency of bone remodeling observed at the initial stage. Therefore, the bone shape and remodeling toward the implant surfaces interfere with the bone-implant contact [18,19]. Carmo Filho, in the study on 4.0 and 4.1 mm diameter implants, reported the decline in implant stability at 21 days after surgery for the hydrophilic SLActive implants to 78.8 ± 2.6 ISQ, and to 78.4 ± 3.2 ISQ at 28 days for hydroxyapatite coated implants. However, hydroxyapatite coated implants regain the secondary stability much faster (42 days) when compared to SLActive implants (68 days) [19].

Regarding the primary stability levels, there is a consensus that ISQ values above 70 are optimal for osteointegration to occur, and they enable the consideration of immediate implant loading. In contrast, the ISQ value of 55 for primary stability is the threshold value for the possibility of leaving the implant in place. Below this value, the implant should be replaced with an implant that enables higher primary stability [18–21]. However, there are studies reporting that modification of the implant's surface in nano-scale allows for successful early loading even in the case of a lower than optimal primary stability level. Östman et al. compared 242 oxidized surface implants, loaded immediately and delayed. Apart from the relatively low primary stability levels (62.9 ± 4.9 ISQ) of immediately loaded implants, the overall success rate was high (99.2%) in that group. Furthermore, the MBL level for immediately loaded implants during 12 months of observation was 0.78 ± 0.9 mm and seems also acceptable [22].

Subsequent studies addressing this subject demonstrated a correlation between low baseline values of RFA and the potential for implant loss due to lack of osteointegration. Sjöström assessed the primary stability value of 17 implants that were lost within the first year of use. It was found that the average ISQ value in that group was 54.6, whereas the implant group with successful treatments had an average ISQ value of 62.0 [23]. Other studies reported an average primary stability value of 63.3 ISQ in the group of implants that survived the 12-month follow-up period, whereas, in the group with lost implants, the average primary stability value was 56 ISQ [24]. Some studies have found a slightly lower (56 ISQ) threshold value for primary stability, which is necessary for osteointegration to occur [25,26]. That is why it seems that, apart from the established consensus, this issue is still a current topic and further studies are needed for its full development.

Aragoneses et al. included the implant diameter in the assessment of the levels of secondary stability. The ISQ value measured three months after the insertion of implants with a diameter of 3.7 mm was 69.62, while for implants with larger diameters (4.0 mm and 4.3 mm), that value was 72.02 and 69.67, respectively [27]. This finding is in agreement with the following study results (Figures 4 and 5).

In the following study, hydrophilic surface implants were applied. The hydrophilic surface is regarded to osteointegrate faster than other commonly used types of surfaces, including sand blasted and acid etched. Novelino et al. reported that hydrophilic surface implants gain a stability of 70 ISQ in less than five weeks which means that it is 2.24 times faster than implants treated with sand blasting and acid etching [20].

The hydrophilic surface implants modified with hydroxyl ion have been assessed for primary and secondary stability only in two other studies to date. Primary stability in the mentioned studies' plants amounted to 57.3 (± 7.4) ISQ and raised to 71.3 (± 8.2) ISQ while loading [28]. The above-mentioned studies mostly focused on measuring the stability of conventionally loaded implants.

An evaluation of the obtained results of MBL shows that they do not deviate from the established norm, according to which MBL should not be greater than 1.5 mm in the first year and then 0.1 mm in each following year. It is important to note that some researchers claim that original remodeling of the alveolar process occurs after implant loading with the aim of restoring biological width [29–33]. However, the condition of the surrounding implant soft tissues seems to play a role in this process. Linkevicius et al. reported significantly lower MBL in a one-year observation when the implant surrounding soft tissue was thicker than 2 mm. The average MBL level in those cases was 0.21 mm and is comparable to our results [29].

The lowest (0.22 ± 0.49 mm) MBL level of early loaded hydrophilic implants with the same, as presented in the following manuscript, observation period (12 months), to date, has been reported by Liaje et al. [30]. This finding of a low MBL was accompanied by high stability values at all time points (above 71 ISQ) and, similar to the presented study findings, (Figure 4) wide implants showed statistically higher stability values than narrow implants. On the contrary, much higher MBL levels than those found in our study for hydrophilic implants were reported by Ryu et al. (0.98 ± 0.61 mm) in 13 months of follow-up, and by Hinkle et al. (0.99 ± 0.29) in 12 months of follow-up [31,32].

In the literature, there are relatively few studies concerning the effects of early loading and changes in stability in connection with MBL. Olsson et al. were among the first who reported the results of studies concerning 68 early-loaded maxillary implants. The value of the average baseline ISQ parameters was 60.1, whereas the implant survival rate was 93.4% and the MBL level was 1.3 ± 0.6 mm at a 12-month follow-up observation [33]. Fischer et al. assessed oxidized-surface implants that were loaded for the period ranging from a few days to 16 days. They achieved an overall success rate of 98.1% and the averaged MBL index was 1.1 mm at a 12-month follow-up observation. In contrast, the ISQ index increased from 63.3 (± 6.1) to 66.8 (± 5.6) after 12 months [24].

The effect of early loading relative to conventional loading on bone tissue levels (without linking with primary stability levels) was also previously studied in other papers. Degidi et al. assessed immediately loaded implants with a diameter of 3 mm, obtaining the MBL level of 0.85 ± 0.71 mm at a 36-month follow-up observation [34]. In studies concerning early-loaded implants (three weeks), Grandi proved efficacy comparable to immediate loading (with a loss of one implant in both groups) at a 12-month follow-up observation. However, a higher average MBL was found in the group of implants loaded after three weeks (0.390 ± 0.840 mm) when compared to immediately-loaded implants (0.120 ± 0.230 mm), with no statistically significant differences between those groups [35]. Other authors report that there is no effect of implant loading time on marginal bone loss. MBL levels in the mentioned studies ranged from 0 to 1.32 mm in longtime observation [36–39].

In our previous studies on conventional SLA implants, the average stability level was initially lower (58.67 ± 12.3 ISQ) than in a following study, and raised to 81 ± 5.82 ISQ six months after implant placement and was accompanied by a mean MBL of 0.22 ± 0.46 , calculated based on radiographs taken in 36-months of follow-up [40].

The present study has some limitations: firstly, the observation period. We decided to evaluate the MBL level in 12 months. In the literature, there exist studies of such methodology; however, the considerable changes in the bone of the alveolar process can occur in the later stages of implant treatment and further studies are needed to confirm all theses of the present study. Secondly, we decided not to measure the stability levels at the final follow-up after 12 months, as the need to remove the implant restoration would emerge under those conditions and could influence implant preservation.

5. Conclusions

With the limitation of our study and 12 months of follow-up, the following conclusions can be made:

- (a) hydrophilic surface implants can be used in a protocol of early functional occlusal loading;
- (b) higher values of primary stability positively influence the values of stability measured four weeks after implantation;
- (c) the age of the patient affects the values of implant stability.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Local Ethical Committee (229/2019).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study. Written informed consent has been obtained from the patients to publish this paper.

Data Availability Statement: Not applicable.

Conflicts of Interest: Thommen Medical (Grenchen, Switzerland), the manufacturer of the dental implants used in this study, provided this trial with dental implants. However, the data is the possession of the authors and the sponsor did not interfere with the course of the trial or in the publication of its results whatsoever. The authors declare no other conflicts of interest that could have influenced the outcomes of this manuscript.

Abbreviations

MSC	mesenchymal stem cells
API	approximal plaque index
CBCT	cone beam computed tomography
RVG	radiovisiography
GDPR	general data protection regulation
ISQ	implant stability quotient
MBL	marginal bone loss
RFA	resonance frequency analysis
SLA	sand blasted acid-etched

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Article

Aesthetic Outcomes of Early Occlusal Loaded SLA Dental Implants with Hydroxyl Ion Modified Surface—A 12 Months Prospective Study

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Abstract: Background: Many efforts have been made recently to arrange a newer, more hydrophilic and more osteoconductive implant surface. One of the possible options in this matter is modification with hydroxyl ion. Materials and Methods: Forty implants with the diameters 3.5 and 4.0 mm were inserted as a single missing tooth restoration protocol in the frontal aspect of the maxilla. All implants were loaded early in a 4 week period. Prior to and during the surgery, the following indices were considered: height of keratinized tissue, the thickness of soft tissue, and the initial level of bone tissue. After 12 months, the implant and the tissues in its direct vicinity were evaluated once more with the following indices: marginal bone loss (MBL), height of keratinized tissue (HKT), probing pocket depth (PPD), pink and white aesthetics scores (PES, WES), as well as pain sensations combined with the procedure (VAS). All results were related to the diameter of the implant and thickness of periodontal biotype. Results: High aesthetic outcomes were reported regardless of soft tissue thickness and implant diameter. The VAS score was higher for the 4.0 implant group, and the thickness of soft tissue had no influence on VAS. In case of implantation in thin or soft tissue, higher MBL levels were reported (0.26 mm), while in case of a thick phenotype, MBL was 0.06 mm. Conclusions: Hydrophilic surface implants can be used for a protocol of early functional occlusal loading. The initial thickness of soft tissue does not influence aesthetic outcomes and does not raise pain perception, although it may elevate crestal bone resorption.

Keywords: dental implant; implant surface modification; early loading; marginal bone loss; periodontal index; pink esthetic score; white esthetic score; PES; WES

1. Introduction

Many factors affect the long-term success rate of implant treatment. One of the most crucial factors is the condition of peri-implant soft tissue. Sufficiently thick mucosa enables the creation of a barrier for bacterial ingrowth and supports a more natural implant emergence profile. Apart of easier to obtain proper hygiene maintenance around implant superstructure, the better esthetics outcome might be achieved in those cases [1].

Both the loading time and the type of prosthetic restoration play a role in supporting the soft tissue in implants' direct vicinity. Previously used cemented restorations due to larger marginal micro-gaps, that could lead to more biofilm accumulation and a higher prevalence of peri-implant infections, were replaced with screw retained restorations [2]. Regarding loading time, previous prosthetic restoration of the implants in case of maxilla were provided within a period of 6 to 8 months. The reason was the need to establish osteointegration [3]. Osteointegration has been defined as a direct and functional connection between bone and an artificial implant. However, from a microscopic point of view, osteointegration manifests as filling the micro-gap between the bone bed and implant

surface with bone tissue. As the bone tissue exhibits relatively low metabolism, it is a time consuming process [4,5].

However, immediate or early loading of a dental implant is especially desirable in implant treatment within the aesthetic zone. It would be beneficial if the healing period could be shortened without jeopardizing the success of the implant treatment [3].

Primary used smooth surface implants, disabled direct bone formation on their surfaces and prolonged osteointegration, secondary stability and furthermore the possibility loading. In the case of such surfaces, the bone overgrowth during implant healing was vectored in just one direction from the implant bed toward the implant surface. Introduction of a new type of rougher implant surface, at a micro scale, allowed for direct bone formation on the implant surface. This made the process of osteointegration bidirectional and shortened the time needed for it to occur [5,6]. While many believe that the possibility for further advances in implant surface microtopography has reached its limitation, significant effort nowadays is paid to the implant surface nanoscale [7–9].

Although newly prepared titanium surfaces are hydrophilic and are characterized by negative electrochemical potential and a stable thin layer of TiO₂, they can be contaminated with an accumulation of non-polar hydrocarbons. This natural process first described by Att et al. was named titanium ageing, and results in changing the electrochemical potential and worsening the wettability of the implant surface [10]. For that reason, the chemical modification of the implant's surface using hydroxyl ions was introduced as one of the options. With such modification, the titanium surface of an implant gains increased negative electrochemical potential.

Aim of the Study

This study was designed to evaluate the hypotheses that implant diameter and soft tissue biotype influence (and if so in what proportion) the aesthetics outcomes, marginal bone loss, and pain sensation combined with the implant procedure. This was in cases of early loaded hydroxyl ion modified SLA (sand-blasted, large grit, acid-etched) implants in 12-month observation. The null hypothesis of the study was that thick, soft tissue biotypes and narrower implant diameters would not improve the value of periodontal indices, as well as aesthetic outcomes and marginal bone loss.

2. Materials and Methods

The present study was designed as a prospective study. The study was performed at Wrocław Medical University Dental Clinical and Teaching facility. The study protocol was approved by a local ethics committee (registration number 229/2019). All patients gave two written consents: the first was general consent to have dental implants placed, and the second involved their participation in this study. The study has been conducted in full compliance with the Declaration of Helsinki, and personal data protection procedures (GDPR) were complied with.

2.1. Inclusion and Exclusion Criteria

This study is in addition to the authors' previous study concerning the early loading of hydroxyl ion modified SLA implants [11], and here, we present the results of the soft tissue parameters that were evaluated.

Details on the specific inclusion and exclusion criteria and the exact clinical procedures were reported in the authors' earlier study [11]. In brief, 40 adult patients needing single implant-supported crown rehabilitation, who could have immediate loading in the upper arch within the aesthetic zone, were enrolled into study. The patients could not have any active periodontal disease or API > 25%. Every participant was subjected to clinical and radiological examinations. The minimum residual bone crest needed to have a minimum width of 7 mm and a minimum height of 13 mm, so that the implant could be placed in the native bone. Furthermore, bone density in the region of the implant insertion should be D2 or D3 acc. to Misch et al. [12]. The randomization was performed on the day of surgery by

drawing a ticket out of an envelope. The patients were randomly divided into 2 groups according to the implant diameters used (3.5 and 4.0 mm) and soft tissue thickness.

Group 1 (G2; $n = 20$ patients)—3.5 mm diameter implants were used

Group 2 (G3; $n = 20$ patients)—4.0 mm diameter implants were used

The guided bone or tissue regeneration procedures were not performed before nor during the implant placement. Furthermore, at least a 3-month healing period after extraction was established.

Remaining exclusion criteria were as follows:

1. systemic or local diseases that could compromise healing or osteointegration,
2. smoking,
3. bruxism,
4. pregnancy,
5. breastfeeding.

All exclusions were done through interview. Additionally, to exclude bruxism, intraoral examination was done to find any dental attrition, masticatory muscle overgrowth, or hyperactivity.

2.2. Protocol of an Experiment

The schedule of visits included the following:

1. Consultation visit: a precondition of the patient for the surgery, clinical and radiological examination CBCT (cone-beam computed tomography) (Galileos[®] D3437, Sirona Dental, Erlangen, Germany), approximal plaque index (API), height of keratinized tissue (HKT) assessment;
2. Implantation: intraoperative and postoperative RVG (radiovisiography—Planmeca OY, Helsinki, Finland), gingival biotype assessment thick/thin;
3. Four weeks after the implantation: intraoral scan, screw-retained prosthetic, RVG;
4. Twelve months after the surgery: clinical evaluation (HKT, probing pocket depth (PPD), Visual Analogue Scale (VAS), pink esthetic score (PES) and white esthetic score (WES)) and radiological assessment (RVG and CBCT).

2.3. Implants

The cylindrical dental implants Thommen Innicell[®]SPI Element MC Innicel (Thommen Medical AG, Grenchen, Switzerland) were used for the surgery. The superhydrophilic surface of the implants was acquired through NaOH conditioning using the Apliquiq system (Thommen Medical AG, Grenchen, Switzerland). The length of the inserted implants ranged from 8 mm to 11 mm and was conditional on the height of the bone base, while the diameter of the implant was determined by the width of the alveolar processes.

2.4. Surgical Phase

The implant surgery included the antibiotic cover of one-shot therapy—1 dose of clindamycin 600 mg (MIP Pharma, Gdansk, Poland). Choice of implant was based on radiological examination performed during the preconditional visit. The implant's surface was conditioned due to insertion with an Apliquiq applicator just before the surgical procedure. Local infiltration anesthesia was provided using Septanest 1:100,000 (SEPTODONT 58, Saint Maur des Fossés, France) with the application of the Wand STA device (Milestone Scientific, Inc. Roseland, NJ, USA). First, a diamond drill on the high-speed hand piece was used for deepithelialization. Then, H-shaped papilla-preservation incision, shifted palatally with a blade no. 15C was done. The implant bed was performed following manufacturer recommendations. During that stage, implants were lifted from the Apliquiq applicator. Subsequently, each implant was inserted at bone level according to the procedure provided by the manufacturer. The partially deepithelialized flap was repositioned and stabilized with 5-0 simple interrupted sutures (Seralene[®], Serag Wiessner, Naila, Germany). At the end of the surgery, an RVG image was done to control the correctness of the im-

plant insertion (Figure 1). The X-ray tubehead was aimed at right angles (vertically and horizontally) to both the implant and the sensor. A paralleling device was used for this purpose. The surgeries were performed by M.K and J.H. Postoperative recommendations included analgesic and anti-inflammatory treatment with Nimesil (Laboratories Menarini SA Barcelona, Spain), 200 mg/per day, and rinsing the oral cavity with Eludril Classic (Pierre Fabre S.A Paris, France) 3 times a day.

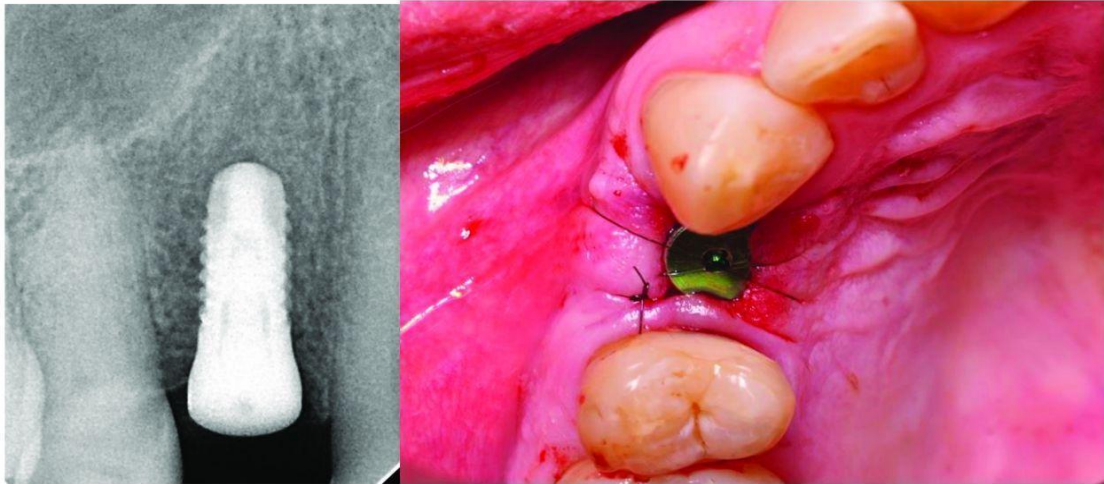


Figure 1. Implant with the healing abutment placed in bicuspid region and left for open healing.

2.5. Prosthetic Phase

The prosthetic restoration stage was conducted 4 weeks after the implant placement surgery and was done by M.K, and J.H. Patients with no signs of inflammation in direct vicinity to the implant were allowed to participate in the prosthetic protocol. Screw-retained implant crowns made of lithium disilicate glass-ceramics, IPS e max CAD LT, were used as prosthetic restorations. After the removal of the healing abutment, the implant bed was cleaned. The scans were taken with an intraoral scanner Sirona Cerec AC Bluecam (DentsplySirona, York, PA, USA) (Figure 2). Subsequently, the surface was etched using IPS Keramik etching gel (Ivoclar Vivadent AG, Schaan, Liechtenstein) and sandblasted using Ti base (DentsplySirona, York, PA, USA), and then the crown was fixed using Monobond Plus bonding agent (Ivoclar Vivadent AG, Schaan, Liechtenstein) and Multilink Hybrid Abutment cement (Ivoclar Vivadent AG, Schaan, Liechtenstein). The crown was then screwed onto the implant with a torque of 25 Ncm. The occluding relations were controlled using articulating paper (Bausch®, Cologne, Germany) with a thickness of 200, 80, and 8 µm. Access to the retaining screw was closed with Gradia composite (GC Corporation, Tokyo, Japan), and an RVG image was taken (Figure 3). The patients were instructed on proper hygiene around the dental implant.

2.6. MBL (Marginal Bone Loss) Assessment Using the Radiological Examination

Prior to the surgery and during 12 months of follow-up, CBCT was performed to assess the marginal bone loss (MBL). The MBL was calculated as follows: first, dimensions were calibrated by the known parameters of implant diameter and length. Starting from the implant shoulder, distances were measured to the mesial and distal points of bone to implant contact, parallel to the implant axis. All measurements were taken by C.O., a member of the research group who was not involved directly in the preparation of the implant.

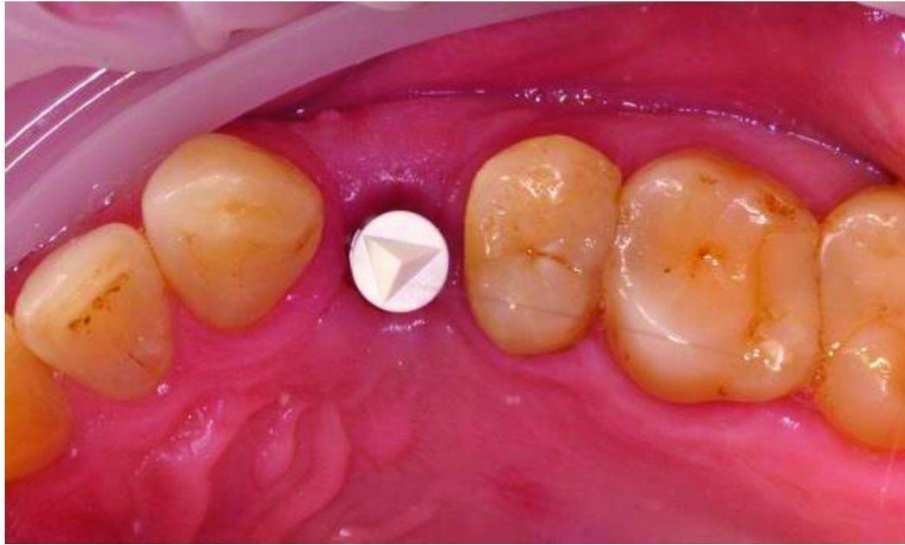


Figure 2. Implant with scanbody prepared for intraoral scan.

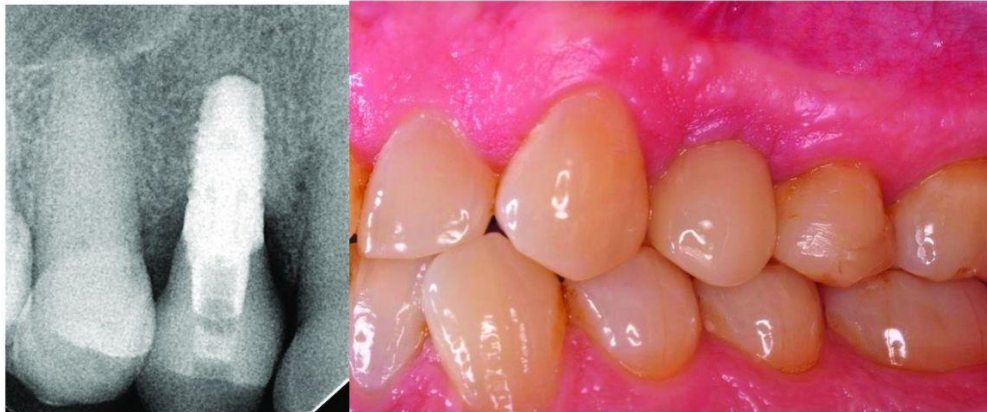


Figure 3. One-year follow-up. Periapical RTG and clinical photography. Implant loaded with the screw-retained crown.

2.7. Periodontal Parameters Measurements

The following clinical parameters were assessed during the study:

- PPD at 4 points (mesial, distal buccal and palatal), measured to the nearest 1 mm using a periodontal probe (Williams Color-Coded Probe, Hu-Friedy Mfg. Co., Chicago, IL, USA);

- HKT using a periodontal probe;

- The thickness of soft tissue was assessed using gingival transparency method by visibility of the underlying periodontal probe, regarding ≥ 2 mm as a thick gingiva.

2.8. Aesthetic Evaluation

The measurements of PES (Pink Esthetic Score) and WES (White Esthetic Score) were done at 12 months according to Belser et al. [13]. Briefly, standardized digital photographs (CanonEOS 650 with ring flash, Canon Inc., Tokyo, Japan) of the aesthetic zone were taken. The peri-implant soft tissue was graded based on five categories: mesial papilla, distal

papilla, curvatures of the facial mucosa, level of the facial mucosa, and root convexity/soft tissue color and texture. To evaluate WES of the visible portion of the implant restoration, five categories were graded: tooth form, outline/volume of clinical crown, color, surface texture, and translucency/characterization. Each of the 5 topics of PES and WES was graded with a 0-1-2 score and resulted in lowest 0 and highest 10 for each of two scores consequently.

2.9. VAS (Visual Analogue Score) Assessment

After a 1-week follow-up, each participant was asked to evaluate his or her pain sensation after the procedure, using a VAS ruler, with zero representing no pain and 10 the worst pain the patient had ever experienced.

2.10. Statistical Analyses

To answer the research questions, statistical analyses were performed using IBM SPSS Statistics 25 software (IBM, New York, PA, USA). The software was used to analyze the basic descriptive statistics together with the U Manna–Whitney test. First, descriptive analysis was done using the χ^2 test. The statistical differences were tested between the 3.5 and 4.0 diameters, and between thick and thin biotype groups. Because group 3.5 and 4.0 were equal, the parametric tests could be used. Hence, the thick and thin biotype groups were not equal, the Pearson's χ^2 test was used.

The relationships between continuous variables were examined by calculating Pearson's linear correlation coefficient. The value of $\alpha = 0.05$ was assumed as the significance level.

To check the distribution of continuous variables and to study their compliance with a normal distribution, basic descriptive statistics were used and the Shapiro–Wilk test of normal distribution was performed. For nominal variables, the frequency and the percentage of individual values in the entire observation pool were calculated.

3. Results

3.1. General Data

Out of 40 implants placed in the surgical phase, each implant achieved osteointegration and consequently high level of secondary stability and was admitted in the prosthetic phase. Furthermore, all implants successfully survived for the 12-month follow-up period.

3.2. Results of MBL

We achieved relatively low levels of MBL for all implants 0.14 mm (± 0.24). However, it was lower within the thick gingival biotype group (0.06) when compared to the thin biotype (0.26). The differences between these two groups were not statistically important. There were also no statistically important differences in that parameter between 3.5 and 4.0 group (0.26 mm (± 0.31) vs. 0.14 mm (± 0.24)) (Tables 1 and 2).

Table 1. Descriptive statistics and the normality test to determine distribution for selected variables for group 3.5 and 4.0. M-Mean, SD-Standard Deviation, t-t distribution, p-probability value.

Variable	Group 3,5		Group 4,0		t	p	d Cohena
	M	SD	M	SD			
MBL	0.26	0.31	0.14	0.24	1.30	0.203	0.43
HKT 0	4.11	1.15	3.75	1.16	0.96	0.344	0.31
HKT 1	4.00	1.30	3.85	0.88	0.43	0.671	0.14
PPD	2.17	0.53	2.04	0.37	0.82	0.417	0.27
VAS	1.53	0.96	1.75	1.33	−0.60	0.554	−0.19
PES	9.50	0.71	9.50	0.71	0.00	1.000	0.00
WES	9.78	0.55	9.72	0.46	0.33	0.744	0.12

Table 2. Descriptive statistics and the normality test to determine distribution for selected variables for group with thin and thick biotype. Differences important statistically are highlighted in red. Me-median, IQR-interquartile range, M-Mean, SD-Standard Deviation, p-probability value.

Variable	Biotype					
	Thin (n = 27)					
	Mean rank	Me	IQR	M	SD	p
MBL	17.76	0.00	0.35	0.19	0.29	0.472
PPD	18.13	2.00	0.75	2.11	0.49	0.709
PES	18.20	10.00	1.00	9.48	0.7	0.736
WES	17.81	10.00	1.00	9.7	0.54	0.35
HKT0	17.57	4.00	1.00	3.64	0.91	0.028
HKT1	17.79	4.00	1.00	3.66	1.01	0.014
VAS	1.79	1	1	1.79	1.29	0.464
	Thick (n = 13)					
	Mean rank	Me	IQR	M	SD	p
MBL	20.72	0.30	0.45	0.24	0.24	0.472
PPD	19.61	2.25	0.56	2.1	0.36	0.709
PES	19.39	10.00	1.00	9.56	0.53	0.736
WES	20.56	10.00	0.00	9.89	0.33	0.35
HKT0	26.18	5.00	2.00	4.64	1.43	0.028
HKT1	27.64	5.00	1.00	4.64	1.02	0.014
VAS	1.29	1	1	1.27	0.47	0.464

3.3. Results of Periodontal Parameters Measurements

The average PPD in 3.5 and 4.0 group implants were comparable: 2.17 mm (± 0.53) vs. 2.04 mm (± 0.37), with no statistically important differences between them. The thickness of soft tissue had no influence on PPD levels as the results of PPD for thick and thin biotype group were the same (2.1 mm) (Table 2). The results of HKT measurements showed statistically important differences between thin and thick biotype group. The HKT slightly improved after 12 months in the thin biotype group, from 3.64 mm (± 0.91) to 3.66 mm (± 1.01), while the thick biotype group remained stable at 4.64 mm (± 1.02) (Table 2). The diameter of the implant had no influence on HKT measurements as there were no statistically important differences between 3.5 and 4.0 groups (Table 1, Figure 4).

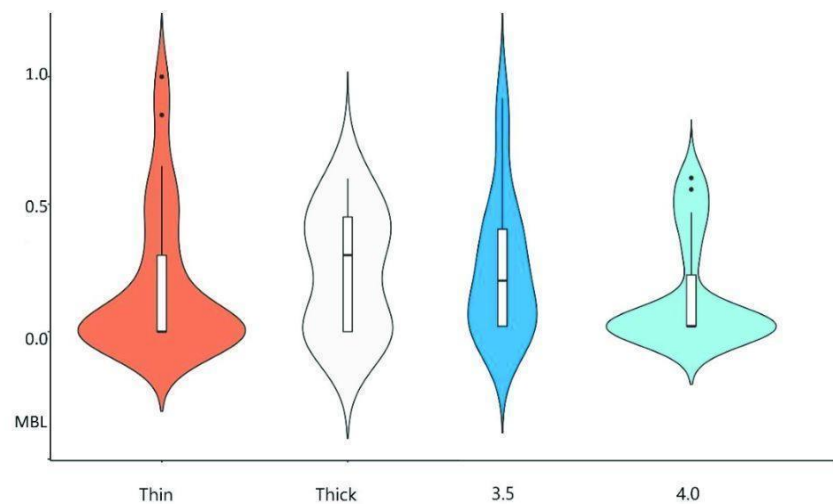


Figure 4. The graphical presentation as a boxplot of MBL results among groups of thick/thin biotype and 3.5/4.0 diameter implants.

3.4. Results of Aesthetic Evaluation

Good aesthetic outcomes were achieved for all implants (Table 1, Figure 1). While there were no differences in pink aesthetics (9.5) for both 3.5 and 4.0 groups, slightly better results were achieved for 3.5 implants in white aesthetics 9.78 vs. 9.72. Thicker biotype of soft tissues moderately improved pink and white aesthetics (9.48 vs. 9.56 and 9.7 vs. 9.89), but with no statistically important differences (Table 2, Figures 5 and 6).

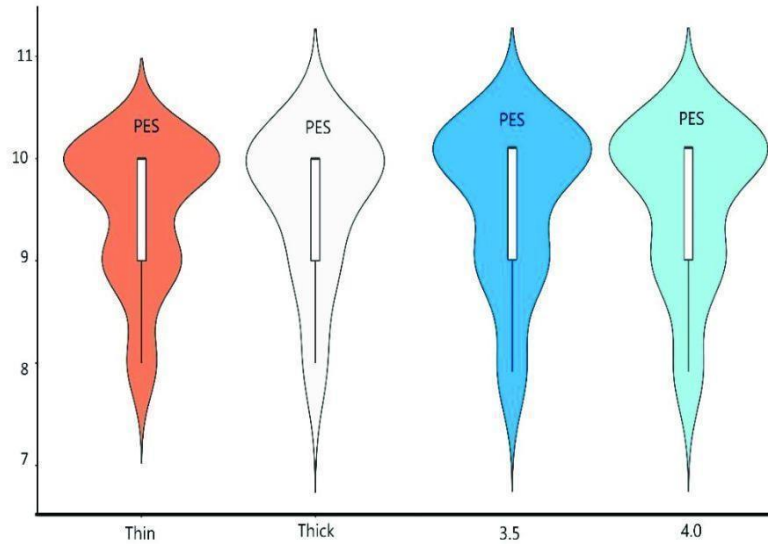


Figure 5. The graphical presentation as a boxplot of PES results among groups of thick/thin biotype and 3.5/4.0 diameter implants.

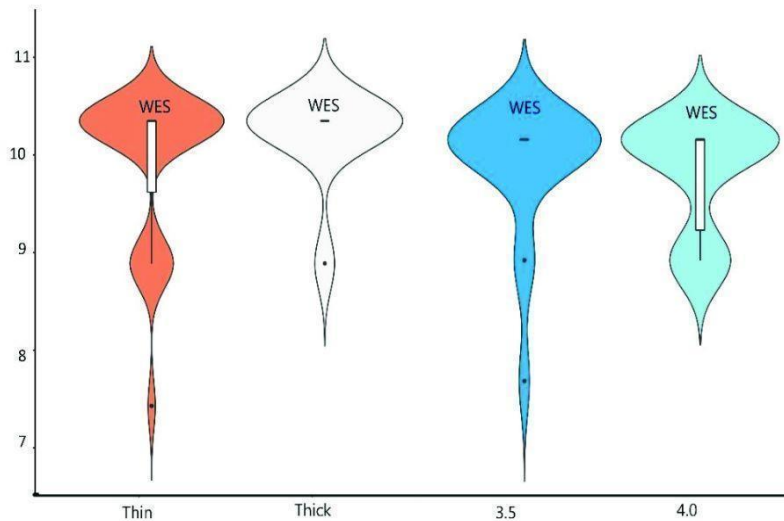


Figure 6. The graphical presentation as a boxplot of WES results among groups of thick/thin biotype and 3.5/4.0 diameter implants.

3.5. Results of VAS Score

There were no statistically important differences in pain sensation after the procedure for both 3.5 and 4.0 groups. The thicker biotype of soft tissues had a slightly smaller VAS score, however without a statistically important difference: 1.27 vs. 1.79.

4. Discussion

The first clinical trial that proposed immediate or early implant loading was conducted in 1990 [14]. Since then, many others studies have proven the safety of such modified treatment protocols, and, moreover, the paradigm of osteointegration necessity for implant loading has been challenged [15,16].

Previously, the most commonly used parameters for evaluating success rate of the implant treatment were related to the implant, the bone and soft tissue in the direct vicinity of the implant, and the prosthesis, apart from the subjective assessment of the patient [17]. These parameters are related to the tissue stability, which influences the progression of marginal bone loss. For decades, the concept of marginal bone loss implied the possibility of 2 mm crestal bone loss in the first year, and up to 0.2 mm every year around the implant neck after functional loading.

However, the recently introduced zero bone loss concept seems to change the paradigm of bone resorption consideration and features a newer point of view on that matter. It is believed that, due to sufficiently thick mucosa, the bone loss around the implant neck can be prevented [18]. The last study of this scope proved the threshold point for soft tissue thickness at 2.88 mm, as such thick soft tissue can prevent bone loss [19,20]. In the present study we decided to exclude patients with previous augmentation procedures, including soft tissue grafts. As a result, in only 11 cases the thick biotype of the gingiva was spotted, while in the majority of cases (29,) we reported a thin biotype. However, even so, the relative low levels of MBL for both thin and thick biotype was reported. None of the patients, regardless of the thickness of soft tissue biotype, even approached the abovementioned proposed levels of MBL. The reason for that finding—in our consideration—might be a relative short observation period. Another explanation for the relatively low MBL could be the fact that most of the patients were characterized by high levels of HKT. This means that even if the soft tissue around the implant's neck was thin, it was at least attached and highly keratinized. Finally, early loading of the implant allows for establishing a peri-implant junction sooner, contributing a biological seal and preventing peri-implant sulcus from bacterial ingrowth. This can provide a higher chance to maintain crestal bone level [21–23]. However, what is worth noticing is that the group of thick biotype was still characterized by statistically important lower MBL levels in comparison to thin biotype.

One of the biggest challenges in implant restoration within the frontal aspect of the maxilla is the aesthetic outcome. However, the primary focus of early literature on maxillary anterior implant outcomes was based on survival parameters, with a lack of information regarding aesthetically relevant parameters. Previously used subjective evaluation was carried out using patient perceptions of the aesthetic outcome, measured by specific questionnaires in which patients express their degree of satisfaction or dissatisfaction. This was replaced with several more reliable objective indices introduced to assess clinician-mediated aesthetic outcomes for single-tooth implant restorations in the aesthetic zone [24–26]. One of the most objective tests to assess aesthetics of the prosthetic restoration is the pink (PES) and white aesthetics scores (WES). PES was first proposed by Furhauser and was lately redefined by Belser et al. [13,27].

The PES according to Belser et al. includes the mesial papilla, distal papilla, soft tissue level, curvature of the facial mucosa, and root convexity/soft tissue color and texture [13]. The height of interdental papilla is especially considered a crucial factor in aesthetics, as it is the most commonly affected part of peri-implant soft tissue. Scientific data demonstrated that the appearance of the papilla in the interproximal area of an implant site is largely dependent on the vertical distance between the alveolar bone crest and contact point, as well as the horizontal distance between the implant and the neighboring implant/tooth [28,29].

A score of ≥ 6 (out of a maximum of 10) for either PES or WES and ≥ 12 (out of a maximum of 20) for PES/WES combined are generally considered satisfactory.

In the present study, generally good aesthetic outcomes were achieved as the overall PES and WES scores were 9.5 and 9.75 and almost reached their maximum. It also shows high average levels of interproximal papilla height. It was suggested that soft tissue thickness might influence the aesthetic scores. However, we did not report such findings. In our study, high level of PES and WES was achieved even if in the vast majority of the cases the soft tissue profile was reported as thin. There can be some explanations for this phenomenon. First, in our consideration, it can be a result of average to good crestal bone level preservation and the supporting function of bone tissue on interproximal papilla height. Second, it is suggested that the fixed prosthesis provided an early contribution to physical support for soft tissue in direct contact around the implant and may result in better soft tissue condition.

Lastly, we decided to include VAS score as a final parameter to be considered in the following study. The reason for that is, apart from good aesthetics outcomes and the general success rate of the implant therapy, any harmful sensation combined with the procedure or healing period might influence final patient satisfaction. Pain associated with the procedure is also one of the major reasons for neglecting or postponing further dental therapy. Generally, pain combined with an early loading protocol as proposed in our study was considered by the patients as acceptably low. The wider implant procedure generated higher pain sensations as the VAS score amounted to 1.75 (± 1.33) for the 4.0 group and 1.53 (± 0.96) for the 3.5 group. The explanation for that finding might be either the need to apply one more drill in the wider implant protocol as well as more time-consuming procedure in that case. The thickness of soft tissue seems not to influence the healing period in the same proportions as in both thick and thin mucosa similar VAS results were achieved.

The literature is missing reports engaging the diameter of the implant or the thickness of the soft tissue with pain related sensations. Generally, as found in the literature, the pain sensations combined with implant insertion might be much higher than reported in the present study. Kim et al. found average VAS score as measured during the procedure to be 4.33 (± 3.30) [30], while Youk et al. reported VAS score at 3.34 for non-template guided implant procedures [31].

Limitations of the Study

The main limitation of the present research is the lack of control group of conventionally loaded implants and early loaded implants with no hydroxyl ion modification. The reason for not including this control group is that early loading protocol with available, commercially non-modified in nano-scale surface implants has been evaluated before by other reports. Other limitations are the short follow-up period. Further research should be conducted to control the achieved results and to evaluate the osteointegration process at its most critical period.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by Local Ethics Committee no 229/2019.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

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Conflicts of Interest: The authors declare no conflict of interest.

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Role of implant loading time in the prevention of marginal bone loss after implant-supported restorations: A targeted review

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D – writing the article; E – critical revision of the article; F – final approval of the article

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Abstract

The implant-supported restoration of missing teeth is a recognized method of treatment that ensures a functional, esthetic and durable effect, along with patient satisfaction. However, the preferable time of dental implant loading is under debate. Currently, 3 protocols are used: immediate loading; early loading; and conventional (late) loading. Immediate loading provides benefits such as short treatment time, the elimination of the second surgery required for later loading protocols, the protection of the gingival papilla, an immediate esthetic effect, and high patient satisfaction. This review aimed to summarize the evidence on the impact of loading time on marginal bone loss (MBL) around dental implants, which is considered a useful measure of implantological treatment effects. A literature search was conducted based on the PubMed/MEDLINE database. The search focused on studies providing the MBL values by protocol. Out of the 1,366 hits received in the initial search, 10 studies were included in the qualitative analysis. At 12 months, the MBL range was 0.17–1.86 mm in patients undergoing the immediate protocol, 0.14–1.22 mm in patients undergoing the early protocol, and 0.44–0.91 mm in patients undergoing the late protocol. The studies were heterogeneous, but no significant differences in the occurrence of MBL were reported between the immediately and early loaded implants as compared with the conventionally loaded ones. Further studies are needed to determine other factors that might be related to the type of protocol, important for optimal patient treatment.

Keywords: dental implants, marginal bone loss, loading protocol, loading time

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Introduction

Dental treatment involving implants is an effective and widely used method of restoring missing teeth, which may result from untreated caries, injuries, tumors, or congenital defects (hypodontia). The reconstruction of missing teeth with the application of implants is a recognized method of treatment. It ensures functional, esthetic and durable restoration, along with patient satisfaction. Over the years, efforts have been made to shorten the duration of implant treatment.

Currently, success in implant therapy is not only based on the implant survival rate and the condition of the tissue in direct implant vicinity, as previously suggested by Albrektsson et al.¹ and Buser et al.,² but also on the full esthetic effect and patient satisfaction. The peri-implant soft tissue, i.e., the pink esthetic score (PES), is assessed using 5 parameters: the mesial papilla; the distal papilla; the curvatures of the facial mucosa; the level of the facial mucosa; and root convexity/soft tissue color and texture. To evaluate the white esthetic score (WES) of the visible portion of the implant restoration, 5 parameters are taken into consideration: the tooth form; the outline/volume of the clinical crown; color; surface texture; and translucency. Each of the 5 parameters of PES and WES was graded with a 0-1-2 score, and consequently, the assessment resulted in the lowest score of 0 and the highest score of 10 for each of the 2 indices.³ High PES and WES scores indicate good condition of soft tissues and esthetic prosthetic reconstruction. In implant-supported prosthetic reconstruction, we can distinguish 3 protocols: immediate loading; early loading; and conventional (late) loading.⁴ All 3 protocols are used for different types of restorations – single, multiple and full-arch.

The extent of marginal bone loss (MBL) is the basic indicator of peri-implantitis. Marginal bone loss is measured from the neck of the implant to the first bone-to-implant contact and is determined during a radiological examination. Marginal bone loss has been considered a useful measure to evaluate the effects of treatment with implants. This review aimed to summarize the current evidence on the impact of loading time on MBL around dental implants.

Methods

A literature search was conducted in the PubMed/MEDLINE database with the use of advanced search options. Only publications in English, studies on humans with an observation period of at least 12 months as determined by authors, and studies published between January 2002 and June 2021 were considered. No restrictions in terms of geographical scope were imposed. Only full-text articles were included; abstracts and posters were excluded. The following search terms and their combinations

were used: ‘implant loading’; ‘protocol’; and ‘marginal bone loss’. The inclusion criteria are reported according to the PICOS criteria and are presented in Table 1. The search was run on February 17, 2022. The list of titles, abstracts and full texts was reviewed by one reviewer according to the defined inclusion and exclusion criteria to identify and select articles related to the topic of interest. The non-systematic approach was used with regard to the qualitative analysis of the identified publications. The extracted data included the loading protocol, the MBL values and the factors affecting the degree of MBL.

Table 1. Inclusion and exclusion criteria

PICOS model	Inclusion criteria	Exclusion criteria
Population	adult human population	animal models
Intervention	implantological treatment	–
Comparison	controlled or single-arm studies	–
Outcome	MBL evaluated during at least 1 year of follow-up	follow-up below 1 year
Study design	RCT, cohort study, case-control study, prospective and retrospective studies	review, meta-analysis, letter to the editor, editorial, opinion

MBL – marginal bone loss; RCT – randomized clinical trial.

Results

After searching PubMed with the use of the keywords related to implantological treatment and its association with MBL, we received 1,366 hits, of which 10 were included in the qualitative analysis. The flowchart of the study is depicted in Fig. 1.

Overall, 10 studies met the inclusion criteria and reported values for MBL, along with definitions of loading protocols; however, they presented data for different follow-up periods and different patient populations. Overall, at 12 months, the MBL values ranged from 0.17 mm

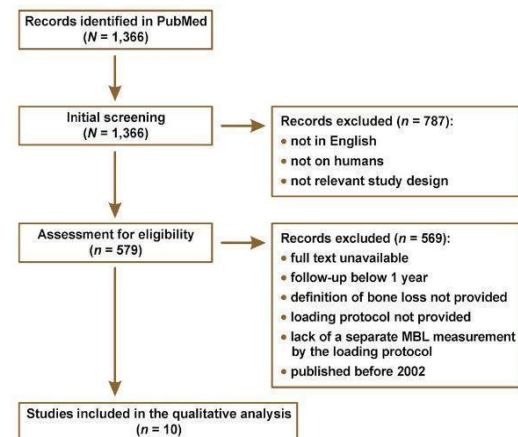


Fig. 1. Flow chart of the study selection process for the systematic review

to 1.86 mm in patients undergoing the immediate protocol, from 0.14 mm to 1.22 mm in patients undergoing the early protocol, and from 0.44 mm to 0.91 mm in patients undergoing the late protocol. The summary of the studies is presented in Table 2.

Discussion

Our review showed that there is still insufficient evidence on the impact of the implant loading protocols on maintaining healthy bone tissue as measured with MBL. Most identified studies concluded that differences in MBL between patients receiving implants according to different loading protocols were not significant. However, a great heterogeneity was observed among studies. They differed in terms of follow-up periods, characteristics of the populations studied, sample sizes, and other factors related to treatment.

Immediate loading

In the literature there is no agreement on the time at which a prosthetic construction is attached to the implant.

Ostman defines immediate loading, also called direct loading, as attaching a prosthetic construction to the implant up to 24 h after implantation.¹⁵ Galli et al. considered 48 h as the maximum time of the restoration placement on the implant.⁸ According to Esposito et al., immediate loading can be defined as taking place up to 7 days after implantation.¹⁶ There is also disagreement with regard to the occlusal contact of crowns or other prosthetic restoration. Some authors claim that prosthetic restorations loaded immediately can be used without occlusal contacts, while others claim that the term “immediate loading” applies only to prosthetic restorations that are in full occlusion, both in centric and eccentric movements.^{17–19} However, there is agreement that the most important criterion for applying the immediate loading protocol is that the implant achieves adequate primary stabilization. This is possible due to a high value of insertion torque, which seems to be crucial in the immediate loading procedure. On the basis of many studies identified in Esposito et al.’s review, this value was determined to be above 35 N·cm.¹⁶

Primary stabilization is the mechanical anchoring of the implant to bone. It enables the correct process of osseointegration, i.e., the direct functional and

Table 2. Characteristics of the selected studies

Author	Study design	Follow-up period	Type of loading	MBL [mm]
Al Amri et al. 2016 ⁵	30 healthy people	2 years	immediate	0.46 ±0.16
	30 T2D patients (HbA1c: 6.1–8.0%)			0.58 ±0.15
	31 T2D patients (HbA1c: 8.1–10.0%)			0.59 ±0.20
Bilhan et al. 2010 ⁶	252 implants in 87 patients	3 years	early (60–90 days)	1.01 ±0.15
			late (91–140 days)	0.90 ±0.18
			late (>140 days)	1.07 ±0.13
Crespi et al. 2007 ⁷	160 implants in 27 patients	18 months	immediate, distal side, maxilla	0.84 ±0.69
			immediate, distal side, mandible	1.24 ±0.60
Galli et al. 2008 ⁸	104 implants in 52 patients	14 months	immediate	1.10 ±0.58
			early	1.11 ±0.54
Gjelvold et al. 2021 ⁹	2 implants	12 months	immediate (smokers)	1.86 ±1.33
	5 implants		late (smokers)	0.91 ±0.66
	22 implants		immediate (non-smokers)	0.37 ±0.55
	18 implants		late (non-smokers)	0.44 ±0.62
Krawiec et al. 2021 ¹⁰	40 implants	12 months	early (within 4 weeks)	0.14 ±0.24
Krawiec et al. 2021 ¹¹	40 implants	12 months	early (within 4 weeks)	0.20 ±0.88
Meijer and Raghoebar 2020 ¹²	15 implants in 15 patients	12 months	immediate	0.17 ±0.73
Pellicer-Chover et al. 2016 ¹³	10 crestal implants	12 months	early	0.06 ±1.11
	13 subcrestal implants			1.22 ±1.06
Zöllner et al. 2008 ¹⁴	383 implants	3 years	total	0.70 ±0.83
			immediate	0.56 ±0.73
			early	0.82 ±0.89

T2D – type 2 diabetes; HbA1c – glycated hemoglobin.

structural connection of bone tissue with the implant surface.^{20,21} Proper primary stabilization is a condition of the implant when movements are sufficiently reduced. Micromovements cannot be completely eliminated, but can be reduced by binding implants together (for example in a bridge), and also by removing lateral contacts, thus diminishing lateral forces.²² Unless primary stabilization is achieved, healing is disturbed by inhibiting osteoblasts. Consequently, connective tissue is formed between the implant and bone (fibrointegration), which results in the loss of the implant. This phenomenon has been studied in animal models.²³

Over the years, many studies have been carried out on factors that may affect primary stabilization, including the following:

- the appropriate preparation of the implant bed¹⁸;
- the use of appropriate techniques, such as osseodensification drilling²⁴;
- the appropriate shape and length of the implant¹⁶;
- the appropriate modification of the implant surface^{10,25};
- the type of implant and the distribution of load^{26,27};
- the condition of bone tissue and its changes during treatment²⁸;
- demographic factors⁹; and
- the type of crown.⁹

The structure of the implant surface is relatively well examined. As previously shown, the appropriate modification of the implant surface, e.g., chemical modification through the immersion of the implant in a special solution¹¹ or acid etching¹⁴, may increase the probability of achieving primary stabilization by the implant at a level that allows its immediate loading.

The use of immediate implant loading provides many benefits. First of all, it reduces treatment time, which positively affects patient satisfaction. The quick restoration of missing teeth increases patient comfort and reduces the negative psychological effects caused by tooth loss.²⁹ Furthermore, the second surgery is avoided to uncover the implant and insert an abutment. With the immediate insertion of a crown, it is more likely to maintain the appropriate tissue contour (especially of the gingival papilla) with a better esthetic result.³⁰ The risk factors for complications that may occur during immediate loading are significant malocclusion, bruxism, a previous implant loss, and any other general contraindications for conventional implantation.

Early loading

Early loading is defined as the implant-prosthetic restoration carried out up to 2–3 months after implantation; however, the average time is 3–6 weeks. This period is critical due to a decline in primary stabilization and still incomplete secondary stabilization.^{15,16,31} Nevertheless, during this time, the primary bone tissue is formed, the mechanical properties of which enable prosthetic

reconstruction. Therefore, it seems reasonable to load the implant 3–4 weeks after implantation. Furthermore, implants with a modified surface achieve secondary stabilization faster than conventional implants.³²

The immediate and early loading of implants have many positive aspects, e.g., fewer surgical interventions, the reduction of soft and hard tissue loss, or the shortening of total treatment time. Those benefits enable basic functions, such as eating, chewing and articulating, to be resumed faster.³³ The use of early or immediate loading is of importance, especially for the esthetic result. This applies to the area between the second right premolar and the second left premolar, which greatly affects the patient's appearance and well-being.

Late loading

The term "late loading" is used when the prosthetic structure is attached late, after the conventional healing period, which lasts at least 3–6 months.^{6,31} This is a 3-step procedure. In the 1st stage, the implant site is allowed to fully heal before loading. During this phase, the osseointegration process occurs. After 3–6 months, the 2nd stage takes place, i.e., the exposure of the implant and the insertion of the healing screw (abutment). The 3rd stage involves placing a prosthetic crown.

Late loading is the most common protocol. One of its advantages is a reduced risk of implant loss after loading.¹⁶ It is recommended in situations where primary stabilization was not achieved using a minimal insertion torque above 20 N·cm, in cases with simultaneous extensive augmentation, or when the patient is not convinced of immediate loading and does not accept the associated risks.

Marginal bone loss

Marginal bone loss is a key parameter that is used to assess the proper healing and functioning of implants.³⁴ This parameter is important, as the gradual loss of bone around the implant may lead to its loss. Researchers report different values of MBL. Despite somewhat varying results, MBL of 2 mm is generally regarded as the maximum acceptable value. During the 1st year after implantation, an acceptable MBL value should be no more than 1.5 mm, with an increase of 0.2 mm per year in subsequent years.^{1,35} Currently, however, it is claimed that no marginal bone atrophy is the only evidence of the adequate healing of the implant (the so-called "zero bone loss concept").³⁶ It is worth considering, especially in young patients, in whom even the 'acceptable' bone loss would amount to 6 mm 20 years after implantation.

Marginal bone loss depends on many factors. One of the most important ones is the thickness of the gingiva around the implants. The critical value is defined as 2 mm; below this value, the risk of atrophy is much higher.³⁷

Other factors include:

- poor oral hygiene⁵;
- the position of the implant in relation to the anatomy of the bone^{13,38};
- the presence of keratinized gingiva^{39,40};
- an improperly made prosthetic restoration⁴¹;
- the type of implant^{42,43};
- the type of prosthetic restoration⁴⁴;
- the type of abutment, and the type of connection between the implant and the abutment^{45,46};
- bruxism⁴⁷;
- tobacco smoking^{9,48};
- a history of periodontal disease^{49,50};
- general diseases, e.g., diabetes^{5,51}; and
- the experience of the operator and the dental technician.^{52,53}

It should be noted that marginal bone atrophy is independent of gender, the degree of primary and secondary stabilization, and the crown-to-implant ratio, while the effect of age is inconclusive.^{54–56}

To assess the MBL value, cone-beam computed tomography (CBCT) or radiovisography (RVG) can be used. In order to correctly determine it, 2 measurements – made on the day of implantation and during the follow-up visit – should be compared. Using the 'As Low As Reasonably Achievable' (ALARA) principle, to minimize the radiation dose, 2 RVG (2–5 microSv) images taken using the right angle technique are sufficient to measure MBL. This ensures the repeatability of the images, and thus the correctness of the measurements.⁵⁷

General considerations

Receiving an answer to the question of whether immediate or early implant loading have important clinical implications as compared to the conventional treatment is important for the physician and the patient, since it enables faster restoration of the functions of the stomatognathic system. Therefore, in recent years, scientists have searched for ways of shortening the time of treatment without affecting its quality. Much research has been conducted to assess the effect of loading time on MBL. A meta-analysis by Esposito et al. showed that there were no significant differences between immediate and conventional loading.¹⁶ In contrast, comparisons between early (6 weeks) and conventional loading as well as between early and immediate loading provide insufficient and inconclusive evidence to determine whether there are any clinically significant differences between the protocols. A meta-analysis by Suarez et al., which included 11 articles, showed that the time of implant loading did not affect MBL.³¹ It was also revealed that after achieving osseointegration, there were no differences between the protocols.³¹ Similar conclusions can be drawn based on other meta-analyses.^{58–61}

The conclusions of the meta-analyses are in line with those of clinical trials, but the latter provide a deeper understanding of other factors that can play a role in the maintenance of proper bone tissue. A prospective controlled clinical trial conducted by De Smet et al. reported that distal implants were more likely to fail in the immediate loading protocol.⁶² According to Kawai and Taylor, the immediately loaded implants showed a loss of about 0.6 mm in the first 12 months, and the same or greater value in the 2nd year.⁶³ Conversely, the implants receiving conventional loading showed almost the same loss as the immediately loaded implants in the 1st year, but resulted in less MBL in the following year.⁶³ Aires and Berger⁶⁴ as well as Crespi et al.⁷ claim that the loading of implants immediately after extraction can be carried out successfully. Bilhan et al.⁶ and Sommer et al.²⁹ indicate that late loading increases the risk of MBL. This is due to the lack of occlusal forces in this protocol, which act on the implant and activate proper bone remodeling. However, in some reports, immediate or early implant loading may be associated with slightly greater MBL, and also with a higher overall risk of implant failure.^{4,65} Discrepancies in the results may be due to many reasons.^{19,65} Possible factors include research bias, a small number of studies available in the literature, small samples sizes, short observation periods, ambiguous definitions of implant loading time, the types of implants and prosthetic reconstruction used, the characteristics of missing teeth (single, multiple, in the mandible, in the maxilla, anterior or lateral), the previously conducted augmentation procedures, whether the reconstruction is made in occlusion or not, etc. Thus, more well-designed and randomized controlled trials (RCTs) in line with the CONSORT (Consolidated Standards of Reporting Trials) guidelines are needed.¹⁶ It is also important that the treating physician understands the healing processes of bone and soft tissue, and performs a thorough examination of the patient's characteristics, which allows selecting the appropriate therapy and avoiding possible complications.

Conclusions

The analysis of the available data leads to the conclusion that there are no statistically significant differences in the occurrence of marginal bone atrophy between the immediately and early loaded implants as compared to the conventionally loaded ones. Nevertheless, immediate and early implant loading are important alternatives for properly selected and compliant patients undergoing treatment according to the guidelines. Further studies are needed to determine other factors, in addition to the type of protocol, to ensure better patient satisfaction.

Ethics approval and consent to participate

Not applicable.

Data availability

All data analyzed during this study is included in this published article.

Consent for publication

Not applicable.

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III. ZAŁĄCZNIKI

1. Informacja o indywidualnym wkładzie współautorów
2. Opinie komisji bioetycznej
3. Wykaz publikacji autora

1. INFORMACJA O WKŁADZIE WSPÓLAUTORÓW

OŚWIADCZENIE WSPÓLAUTORÓW

Early Loading of Titanium Dental Implants with Hydroxyl Ion Modified Surface: A 12-Month Prospective Clinical Trial

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OŚWIADCZENIE WSPÓLAUTORÓW

Aesthetic Outcomes of Early Occlusal Loaded SLA Dental Implants with Hydroxyl Ion Modified Surface—A 12 Months Prospective Study

Maciej Krawiec, Jakub Hadzik, Cyprian Olchowy, Marzena Dominiak and Paweł Kubasiewicz-Ross

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E- Analiza statystyczna	
F- Przegląd piśmiennictwa	
G- Napisanie ostatecznej wersji manuskryptu	
H- Nadzór merytoryczny	
I- Pozyskanie Finansowania	

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OŚWIADCZENIE WSPÓLAUTORÓW

Role of implant loading time in the prevention of marginal bone loss after implant-supported restorations: A targeted review

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Jakub Hadzik	B,C,D,F
Marzena Dominiak	A,C,E,F

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B- Zebranie danych
C- Analiza danych i interpretacja
D- Napisanie artykułu
E- Nadzór merytoryczny
F- Ostateczne zatwierdzenie artykułu

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2. ZGODA KOMISJI BIOETYCZNEJ

1

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OPINIA KOMISJI BIOETYCZNEJ Nr KB – 596/2018

Komisja Bioetyczna przy Uniwersytecie Medycznym we Wrocławiu, powołana zarządzeniem Rektora Uniwersytetu Medycznego we Wrocławiu nr 133/XV R/2017 z dnia 21 grudnia 2017 r. oraz działająca w trybie przewidzianym rozporządzeniem Ministra Zdrowia i Opieki Społecznej z dnia 11 maja 1999 r. (Dz.U. nr 47, poz. 480) na podstawie ustawy o zawodzie lekarza z dnia 5 grudnia 1996 r. (Dz.U. nr 28 z 1997 r. poz. 152 z późniejszymi zmianami) w składzie:

dr hab. Jacek Daroszewski (endokrynologia, diabetologia)
prof. dr hab. Krzysztof Grabowski (chirurgia)
dr Henryk Kaczkowski (chirurgia szczękowa, chirurgia stomatologiczna)
mgr Irena Knabel-Krzyszowska (farmacja)
prof. dr hab. Jerzy Liebhart (choroby wewnętrzne, alergologia)
ks. dr hab. Piotr Mrzygłód (duchowny)
mgr Luiza Müller (prawo)
dr hab. Sławomir Sidorowicz (psychiatria)
dr hab. Leszek Szenborn (pediatria, choroby zakaźne)
Danuta Tarkowska (pielęgniarstwo)
prof. dr hab. Anna Wiela-Hojeńska (farmakologia kliniczna)
dr hab. Andrzej Wojnar (histopatologia, dermatologia) przedstawiciel Dolnośląskiej Izby Lekarskiej)
dr hab. Jacek Zieliński (filozofia)

pod przewodnictwem
prof. dr hab. Jana Kornafela (ginekologia i położnictwo, onkologia)

Przestrzegając w działalności zasad Good Clinical Practice oraz zasad Deklaracji Helsińskiej, po zapoznaniu się z projektem badawczym pt.

„Porównawcza ocena stabilizacji dwóch rodzajów implantów o różnej średnicy platformy w stosunku do poziomu wyrostka zębodołowego i wysokości brodawki międzyzębowej w strefie estetycznej szczęki”

zgłoszonym przez **lek. dent. Macieja Krawca** zatrudnionego w Katedrze i Zakładzie Chirurgii Stomatologicznej Uniwersytetu Medycznego we Wrocławiu oraz złożonymi wraz z wnioskiem dokumentami, w tajnym głosowaniu postanowiła wyrazić zgodę na przeprowadzenie badania w Katedrze i Zakładzie Chirurgii Stomatologicznej UM **pod warunkiem zachowania anonimowości uzyskanych danych.**

Uwaga: Badanie to zostało objęte ubezpieczeniem odpowiedzialności cywilnej Uniwersytetu Medycznego we Wrocławiu z tytułu prowadzonej działalności:

Pouczenie: W ciągu 14 dni od otrzymania decyzji wnioskodawcy przysługuje prawo odwołania do Komisji Odwoławczej za pośrednictwem Komisji Bioetycznej UM we Wrocławiu

Opinia powyższa dotyczy: projektu badawczego będącego podstawą działalności statutowej

Wrocław, dnia **26** października 2018 r.

BW

Uniwersytet Medyczny we Wrocławiu
KOMISJA BIOETYCZNA
przewodniczący
prof. dr hab. Jan Komafel

KOMISJA BIOETYCZNA
przy
Uniwersytecie Medycznym
we Wrocławiu
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OPINIA KOMISJI BIOETYCZNEJ Nr KB – 229/2019

Komisja Bioetyczna przy Uniwersytecie Medycznym we Wrocławiu, powołana zarządzeniem Rektora Uniwersytetu Medycznego we Wrocławiu nr 133/XV R/2017 z dnia 21 grudnia 2017 r. oraz działająca w trybie przewidzianym rozporządzeniem Ministra Zdrowia i Opieki Społecznej z dnia 11 maja 1999 r. (Dz.U. nr 47, poz. 480) na podstawie ustawy o zawodzie lekarza z dnia 5 grudnia 1996 r. (Dz.U. nr 28 z 1997 r. poz. 152 z późniejszymi zmianami) w składzie:

dr hab. Jacek Daroszewski, prof. nadzw. (endokrynologia, diabetologia)
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dr hab. Andrzej Wojnar, prof. nadzw. (histopatologia, dermatologia) przedstawiciel
Dolnośląskiej Izby Lekarskiej)
dr hab. Jacek Zieliński (filozofia)

pod przewodnictwem

prof. dr hab. Jana Kornafela (ginekologia i położnictwo, onkologia)

Przestrzegając w działalności zasad Good Clinical Practice oraz zasad Deklaracji Helsińskiej, po zapoznaniu się z projektem badawczym pt.:

„Porównawcza ocena stabilizacji dwóch rodzajów implantów o różnej średnicy platformy w stosunku do wczesnego, funkcjonalnego obciążenia implantów i poziomu witaminy D we krwi włośniczkowej”

zgłoszonym przez **lek. dent. Macieja Krawca** zatrudniony w Katedrze i Zakładzie Chirurgii Stomatologicznej Uniwersytetu Medycznego we Wrocławiu oraz złożonymi wraz z wnioskiem dokumentami, w tajnym głosowaniu postanowiła **wyrazić zgodę** na przeprowadzenie badania w Katedrze i Zakładzie Chirurgii Stomatologicznej pod nadzorem prof. dr hab. Marzeny Dominiak **pod warunkiem zachowania anonimowości uzyskanych danych**.

Uwaga: Badanie to zostało objęte ubezpieczeniem odpowiedzialności cywilnej Uniwersytetu Medycznego we Wrocławiu z tytułu prowadzonej działalności.

Pouczenie: W ciągu 14 dni od otrzymania decyzji wnioskodawcy przysługuje prawo odwołania do Komisji Odwoławczej za pośrednictwem Komisji Bioetycznej UM we Wrocławiu.

Opinia powyższa dotyczy projektu badawczego będącego podstawą rozprawy doktorskiej.

Wrocław, dnia 8 marca 2019 r.

Uniwersytet Medyczny we Wrocławiu
KOMISJA BIOETYCZNA
przewodniczący

prof. dr hab. Jan Kornafel

3. WYKAZ PUBLIKACJI AUTORA

Wykaz publikacji

MACIEJ KRAWIEC

1. Publikacje w czasopismach naukowych

1.1 Publikacje w czasopiśmie naukowym posiadającym Impact Factor

Lp	Opis bibliograficzny	IF	PK
1.	Comparative evaluation of the effectiveness of the implantation in the lateral part of the mandible between short tissue level (TE) and bone level (BL) implant systems. [AUT.] JAKUB HADZIK, UTE BOTZENHART, MACIEJ KRAWIEC , TOMASZ GEDRANGE, FRIEDHELM HEINEMANN, ANDRAS VEGH, MARZENA DOMINIAK. Ann.Anat. 2017 Vol.213 s.78-82, ryc., tab., bibliogr. 27 poz., summ. DOI: 10.1016/j.aanat.2017.05.008	1,852	30,00
2.	Short implants and conventional implants in the residual maxillary alveolar ridge: a 36-month follow-up observation. [AUT.] JAKUB HADZIK, MACIEJ KRAWIEC , PAWEŁ KUBASIEWICZ-ROSS, AGATA PRYLIŃSKA-CZYŻEWSKA, TOMASZ GEDRANGE, MARZENA DOMINIAK. Med.Sci.Monit. 2018 Vol.24 s.5645-5652, ryc., tab., bibliogr. 33 poz., summ. DOI: 10.12659/MSM.910404	1,980	20,00
3.	The influence of the crown-implant ratio on the crestal bone level and implant secondary stability: 36-month clinical study. [AUT.] JAKUB HADZIK, MACIEJ KRAWIEC , KONSTANTY SŁAWECKI, CHRISTIANE KUNERT-KEIL, MARZENA DOMINIAK, TOMASZ GEDRANGE. BioMed Res.Int. 2018 Vol.2018 art.4246874 [7 s.], ryc., tab., bibliogr. 42 poz., summ. DOI: 10.1155/2018/4246874	2,197	25,00
4.	Aesthetic outcomes of early occlusal loaded SLA dental implants with hydroxyl ion modified surface - a 12 months prospective study. [AUT.] MACIEJ KRAWIEC , JAKUB HADZIK, CYPRIAN OLCHOWY, MARZENA DOMINIAK, PAWEŁ KUBASIEWICZ-ROSS. Materials 2021 Vol.14 no.21 art.6353 [12 s.], ryc., tab., bibliogr. 31 poz., summ. DOI: 10.3390/ma14216353	3,623*	140,00
5.	Early loading of titanium dental implants with hydroxyl ion modified surface: a 12-month prospective clinical trial. [AUT.] MACIEJ KRAWIEC , JAKUB HADZIK, MARZENA DOMINIAK, WOJCIECH GRZEBIELUCH, ARTUR BŁASZCZYSZYN, PAWEŁ KUBASIEWICZ-ROSS. Appl.Sci. 2021 Vol.11 no.7 art.2958 [13 s.], ryc., tab., bibliogr. 40 poz., summ. DOI: 10.3390/app11072958	2,679*	100,00
		12,331	315,00

*IF 2020

1.2 Publikacje w czasopiśmie naukowym nieposiadającym IF

Lp	Opis bibliograficzny	PK
1.	Kamica ślinianki podżuchwowej - opis przypadku (Submandibular sialolithiasis - case report). [AUT.] MACIEJ KRAWIEC , PAWEŁ KUBASIEWICZ-ROSS, WIKTOR SIDOROWICZ, ANNA PELC, PIOTR KAPEK. Twój Przegl.Stomatol. 2015 nr 10 s.42-44, ryc., streszcz., summ.	3,00
2.	Autotransplantacja jako metoda autogennej rekonstrukcji ubytków wyrostka zębodołowego - opis przypadku (Autotransplantation as a method of autogenous reconstruction of alveolar bone loss - a case report). [AUT.] MARZENA DOMINIAK, MACIEJ KRAWIEC , ARTUR PITUŁAJ, ANNA SMULCZYŃSKA-DEMEL, IWONA BEDNARZ. Laser-wyd.pol. 2017 Vol.4 nr 4 s.22-29, ryc., bibliogr. 17 poz., streszcz., summ.	0,00
3.	The role of vitamin D in the human body with a special emphasis on dental issues: literature review. [AUT.] MACIEJ KRAWIEC , MARZENA DOMINIAK. Dent.Med.Probl. 2018 Vol.55 no.4 s.419-424, tab., bibliogr. 41 poz., summ. DOI: 10.17219/dmp/99051	11,00
4.	Prospective evaluation of vitamin D levels in dental treated patients: a screening study. [AUT.] MACIEJ KRAWIEC , MARZENA DOMINIAK. Dent.Med.Probl. 2021 Vol.58 no.3 s.321-326, ryc., tab., bibliogr. 34 poz., summ. DOI: 10.17219/dmp/134911	70,00

5.	Role of implant loading time in the prevention of marginal bone loss after implant-supported restorations: A targeted review. [AUT.] MACIEJ KRAWIEC , CYPRIAN OLCHOWY, PAWEŁ KUBASIEWICZ-ROSS, JAKUB HADZIK, MARZENA DOMINIAK. Dent.Med.Probl. 2022 May 24. Online ahead of print. DOI: 10.17219/dmp/150111	84,00
		154,00

1.3 Prace kontrybutorskie – uczestnictwo w grupie badawczej –

2. Monografie naukowe i skrypty

2.1 Autorstwo monografii naukowej –

2.2 Autorstwo rozdziału w monografii naukowej –

2.2.1 Autorstwo rozdziału w monografii pokonferencyjnej –

2.3 Redakcja naukowa monografii naukowej –

3 Inne –

4. Streszczenia zjazdowe

Lp	Opis bibliograficzny
1.	Comparative evaluation of the effectiveness of the implantation in the lateral part of the mandible using short implants. [AUT.] MARZENA DOMINIAK, MACIEJ KRAWIEC , TOMASZ GEDRANGE. Int.Dent.J. 2015 Vol.65 suppl.2 s.79 poz.FC159, The 103rd FDI Annual World Dental Congress. Bangkok (Thailand),22-25 September 2015. Abstracts.
2.	Comparative evaluation of short tissue level (TE) and bone level (BL) dental implants. [AUT.] JAKUB HADZIK, PAWEŁ KUBASIEWICZ-ROSS, MACIEJ KRAWIEC , ARTUR PITUŁAJ, TOMASZ GEDRANGE, MARZENA DOMINIAK. W: Nowe horyzonty radiologii stomatologicznej : 40 lat akademickiego nauczania radiologii stomatologicznej w Lublinie. Lublin, 21-23 października 2016 r. Streszczenia i prezentacje, s.124.
3.	Comparative evaluation of the effectiveness of the implantation in the lateral part of the mandible between short tissue level (TE) and bone level (BL) implant systems. [AUT.] JAKUB HADZIK, MACIEJ KRAWIEC , UTE BOTZENHART, TOMASZ GEDRANGE, MARZENA DOMINIAK. Int.Dent.J. 2016 Vol.66 suppl.1 s.50 poz.P054, 104th FDI Annual World Dental Congress. Poznań (Poland), 7-10 September 2016. Abstracts.
4.	Micro-CT evaluation of modified zirconia implants osteointegration. [AUT.] ARTUR PITUŁAJ, PAWEŁ KUBASIEWICZ-ROSS, JAKUB HADZIK, KAMIL JURCZYSZYN, MACIEJ KRAWIEC , MARZENA DOMINIAK. W: Nowe horyzonty radiologii stomatologicznej : 40 lat akademickiego nauczania radiologii stomatologicznej w Lublinie. Lublin, 21-23 października 2016 r. Streszczenia i prezentacje, s.122.
5.	Rola witaminy D w leczeniu stomatologicznym na podstawie badań własnych. [AUT.] MACIEJ KRAWIEC , MARZENA DOMINIAK. Public Health Forum 2016 Vol.2 no.3 s.185-186, II Międzynarodowy Kongres Polskiego Towarzystwa Zdrowia Publicznego "Zdrowie publiczne - efektywnie wykorzystać zasoby ochrony zdrowia". Wrocław, 24-25 XI 2016 r. Streszczenia.
6.	Short-implants and conventional implants in the residual maxillary alveolar ridge - 36-month follow-up observation. [AUT.] J[AKUB] HADZIK, M[ACIEJ] KRAWIEC , P[AWEŁ] KUBASIEWICZ-ROSS, K[ONSTANTY] SŁAWECKI, T[OMASZ] GEDRANGE, M[ARZENA] DOMINIAK. Clin.Oral Implant.Res. 2016 Vol.27 suppl.13 s.201 poz.PSA-304, 25th European Association for Osseointegration EAO Congress. Paris (France), 29 September - 1 October 2016. Abstracts.
7.	The effectiveness of short implants in the posterior mandible. [AUT.] ARKADIUSZ MAKOWIECKI, MACIEJ KRAWIEC , MARZENA DOMINIAK. Int.Dent.J. 2016 Vol.66 suppl.1 s.11 poz.FC028, 104th FDI Annual World Dental Congress. Poznań (Poland), 7-10 September 2016. Abstracts.
8.	6 mm and 8 mm dental implants in mandible - 12 months follow-up. [AUT.] MACIEJ KRAWIEC , JAKUB HADZIK, SYLWIA HNITECKA, MARZENA DOMINIAK. Int.Dent.J. 2017 Vol.67 suppl.1 s.37-38 poz.P023, 105th FDI Annual World Dental Congress. Madrid (Spain), 29 August - 1 September 2017. Abstracts.
9.	Influence of the crown-implant-ratio on crestal bone and implant stability. [AUT.] JAKUB HADZIK, PAWEŁ KUBASIEWICZ-ROSS, MACIEJ KRAWIEC , TOMASZ GEDRANGE, MARZENA DOMINIAK. Int.Dent.J. 2017 Vol.67 suppl.1 s.15-16 poz.FC045, 105th FDI Annual World Dental Congress. Madrid (Spain), 29 August - 1 September 2017. Abstracts.

10.	Vitamin-D in dental treatment on the basis of own research. [AUT.] MACIEJ KRAWIEC , MARZENA DOMINIAK. Int.Dent.J. 2017 Vol.67 suppl.1 s.31 poz.P002, 105th FDI Annual World Dental Congress. Madrid (Spain), 29 August - 1 September 2017. Abstracts.
11.	Non-splinted single tooth restorations based on short implants in maxilla. [AUT.] JAKUB HADZIK, MACIEJ KRAWIEC , PAWEŁ KUBASIEWICZ-ROSS, TOMASZ GEDRANGE, MARZENA DOMINIAK. Int.Dent.J. 2018 Vol.68 suppl.2 s.40 poz.P069, 106th FDI World Dental Congress. Buenos Aires (Argentina), 5-8 September 2018. Abstracts. DOI: 10.1111/idj.12441
12.	Non-splinted single tooth restorations based on short implants in maxilla a follow-up study. [AUT.] JAKUB HADZIK, MACIEJ KRAWIEC , PAWEŁ KUBASIEWICZ-ROSS, MARZENA DOMINIAK. Clin.Oral Implant.Res. 2018 Vol.29 suppl.17 s.335 poz.10624, 27th Annual Scientific Meeting of the European Association for Osseointegration. Vienna, 11-13 October 2018. DOI: 10.1111/clr.220_13358

Impact factor: 12,331 (liczba prac: 5)

	Punktacja MNiSW
do roku 2018	89,0
od roku 2019	380,0
Razem:	469,0

2.06.2022r. Monika Górska

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