

UNIWERSYTET MEDYCZNY IM. PIASTÓW ŚLĄSKICH WE WROCŁAWIU

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Ocena przydatności sonoelastografii fali poprzecznej w diagnostyce i leczeniu zwiększonego napięcia mięśni żwaczy w przebiegu dysfunkcji narządu żucia

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Pragnę złożyć najserdeczniejsze podziękowania Promotorowi mojej pracy, prof. dr hab. n. med. Mieszkowi Więckiewiczowi za wsparcie, życzliwość, zaufanie i opiekę podczas studiów doktoranckich oraz wiele cennych wskazówek w pracy naukowej i klinicznej.

> Niniejszą pracę dedykuję mojemu Mężowi i wspaniałym Dzieciom za nieustającą motywację, ogromne wsparcie i pomoc. Wasza wiara we mnie uskrzydla...

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I. STRESZCZENIE

Dysfunkcje narządu żucia (temporomandibular disorders, TMD) stanowią poważny problem diagnostyczno-leczniczy i mogą dotyczyć od 10-90% populacji. Do charakterystycznych objawów należą ból mięśni narządu żucia i/lub stawów skroniowo-żuchwowych, objawy dźwiękowe w stawach skroniowo-żuchwowych (trzaski, trzeszczenie) oraz zaburzenia ruchomości żuchwy. Dodatkowo mogą występować objawy z otaczających tkanek. Brak obiektywnych narzędzi diagnostycznych może utrudniać i opóźnić proces terapeutyczny. Pomiar napięcia mięśni żwaczy wykonany w oparciu o metodę sonoelastografii fali poprzecznej (shear wave elastography, SWE) może wypełnić tą lukę.

Celem pracy była ocena przydatności sonoelastografii fali poprzecznej w diagnostyce i ocenie efektów leczenia zwiększonej sztywności mięśni żwaczy w przebiegu TMD.

W badaniu ustalono wartości referencyjne sztywności mięśnia żwacza u zdrowych ochotników. Wiek i płeć były istotnymi czynnikami wpływających na sztywność mięśni żwaczy. Zgodnie z otrzymanymi wynikami, ogólna średnia sztywność wyniosła 10,67 \pm 1,77 kPa. Średnie wartości były niższe o 2,25 kPa (9,15%) u kobiet w porównaniu z mężczyznami (9,48 \pm 1,47 kPa vs 11,73 \pm 1,27 kPa; p < 0,0001). Wartości sztywności wzrastały wraz z wiekiem, przy współczynniku korelacji około 0,35 i p < 0,0001. Ustalenie wartości referencyjnych badania sztywności mięśni żwaczy metodą sonoelastografii fali poprzecznej stanowiło punkt wyjściowy do dalszych badań. W 8 tygodniowym badaniu przeprowadzonym wśród pacjentów poddawanych leczeniu zachowawczemu TMD (terapia manualna wraz z szyną zwarciową) oceniono skuteczność leczenia w sposób obiektywny (sonoelastografia) i subiektywny (walidowane kwestionariusze). Wyniki badania wskazały, że po leczeniu sztywność obu mięśni żwaczy uległa znacznemu zmniejszeniu (o średnio 4,21 kPa), a pacjenci raportowali znaczne ograniczenie bólu. Subiektywna poprawa przełożyła się na zmniejszenie sztywności mięśni żwaczy, a zatem sonoelastografia wykazała swoją użyteczność w ocenie postępów leczenia u pacjentów z TMD.

W wyniku przeprowadzonych badań można stwierdzić, że sonoelastografia fali poprzecznej jest obiektywnym narzędziem do oceny sztywności mięśni żwaczy u pacjentów oraz oceny prowadzonego leczenia u pacjentów z TMD. Dzięki sonoelastografii można obiektywnie porównywać grupy pacjentów oraz oceniać efekty leczenia na przestrzeni czasu. Sonoelastografia jest bezpieczna, nieinwazyjna i nie powoduje negatywnych doznań u pacjentów.

II. ABSTRACT

Temporomandibular disorders (TMD) is a serious diagnostic and therapeutic problem and may affect 10-90% of the population. Characteristic symptoms include pain in the masticatory muscles and/or temporomandibular joints, sounds in the temporomandibular joints (clicking and popping), and abnormal jaw movements. Additionally, patients may complain about the surrounding structures. The lack of objective diagnostic tools may hamper and delay the therapeutic process. Measurement of masseter muscle stiffness based on the shear wave elastography (SWE) method can fill this gap.

The aim of the study was to evaluate the usefulness of SWE in the diagnosis and evaluation of the treatment effects of increased masseter muscle stiffness in the course of TMD.

The study determined the reference values for the stiffness of the masseter muscle in healthy volunteers. Age and gender were important factors affecting the stiffness of the masseter muscle. According to the results achieved, the overall mean elasticity was 10.67 ± 1.77 kPa. The average values were lower by 2.25 kPa (9.15%) in women compared to men (9.48±1.47 kPa vs. 11.73±1.27 kPa; p < 0.0001). The stiffness values increased with age, with a correlation coefficient of about 0.35 and a p < 0.0001.

The determination of reference values for the study of masseter muscle stiffness using shear wave sonoelastography was the starting point for further studies. In an 8-week study conducted among patients who underwent conservative treatment for TMD (manual therapy with an occlusal splint), the effectiveness of treatment was objectively assessed with sonoelastography and subjectively assessed with validated questionnaires. The results showed that after treatment, the stiffness of both masseter muscles decreased significantly (by 4.21 kPa). The patients reported a significant reduction in pain. The subjective improvement translated into a reduction in masseter muscle stiffness, and therefore SWE has shown its usefulness in assessing treatment progress in patients with TMD.

As a result of the research conducted, it can be concluded that SWE is an objective tool to assess the stiffness of the masseter muscles and to evaluate the treatment in patients with TMD. Thanks to sonoelastography, it is possible to objectively compare groups of patients and evaluate the effects of treatment over time. Sonoelastography is safe, noninvasive and free of negative experiences for the patient.

III. WSTĘP

Dysfunkcje narządu żucia, nazywane również zaburzeniami skroniowo-żuchwowymi (temporomandibular disorders, TMD) stanowią poważny i częsty problem diagnostycznoleczniczy w praktyce stomatologicznej. Ich objawy stwierdza się u 10-90% społeczeństwa w zależności od badanej populacji. [1, 2] Szacuje się, że w polskiej populacji osób zdrowych odsetek ten wynosi 55,9%. [3] Do najbardziej charakterystycznych objawów zalicza się ostry lub przewlekły ból mięśni narządu żucia i/lub stawów skroniowo-żuchwowych, objawy dźwiękowe w stawach skroniowo-żuchwowych (trzaski, trzeszczenie) oraz zaburzone ruchy żuchwy. [4] Podstawowym objawom mogą towarzyszyć dolegliwości z otaczających tkanek, a pacjenci uskarżają się na bóle głowy, zaburzenia otolaryngologiczne, a także zwiększenie napięcia i ból mięśni szyi i obręczy barkowej. [5, 6] Patologie mięśni żwaczy powodują osłabienie siły zgryzu i morfologii zgryzu, zaburzenia mowy oraz ostry lub przewlekły ból. [7, 8] Przegląd literatury dokonany przez Cuccię i Caradonna sugeruje, że zmienione napięcie w układzie stomatognatycznym może mieć konsekwencje dla całego organizmu. [9] W badaniu przedmiotowym pacjentów z TMD stwierdza się zwiększone napięcie mięśni żwaczy często współwystępujące z ich przerostem oraz bolesnością uciskowa. Diagnostyka TMD opiera się na ustandaryzowanych, międzynarodowych, walidowanych kryteriach Diagnostic Criteria for Temporomandibular Disorders (DC-TMD). [10, 11]

Patogeneza TMD jest niejasna i wieloczynnikowa. [12] Na funkcjonowanie układu stomatognatycznego i ogólne utrzymanie zdrowia jamy ustnej wpływa wiele czynników. Stwierdzono, że nawyki parafunkcyjne są istotnie związane z występowaniem objawów TMD. [13] Do ogólnych czynników zalicza się czynniki behawioralne (zgrzytanie, zaciskanie i nieprawidłowa pozycja głowy), czynniki społeczne (wpływające na percepcję i wyuczoną reakcję na ból), czynniki emocjonalne (depresja i lęk), oraz czynniki poznawcze. [12] Biorąc pod uwagę powyższe czynniki, diagnostyka TMD przysparza wiele trudności związanych z utrudnionym różnicowaniem z powodu braku obiektywnych narzędzi diagnostycznych, późnego zgłaszania się pacjentów do specjalistów oraz możliwości występowania chorób współistniejących. Późna lub błędna diagnoza oraz opóźnione leczenie przyczyniają się do chronifikacji dolegliwości. [14]

Głównym celem leczenia pacjentów z TMD jest zmniejszenie napięcia i wyeliminowanie bólu mięśni narządu żucia oraz przywrócenie prawidłowej funkcji stawów skroniowo-żuchwowych. Wstępne badanie najczęściej wykonane jest przez stomatologa i

obejmuje wywiad, następnie ocenę symetrii twarzy i łuku zgryzowego, badanie palpacyjne mięśni żucia i stawów skroniowo-żuchwowych, badanie całego uzębienia pod kątem liczby i położenia zębów wraz z ich powierzchnią. [15] Pacjenci w pierwszej kolejności są kierowani do leczenia zachowawczego, a następnie w przypadku niepowodzenia na leczenie chirurgiczne. [16, 17] Konserwatywne strategie leczenia mają na celu zmniejszenie bólu spowodowanego przez TMD i przywrócenie prawidłowej funkcji narządu żucia. Stosuje się szeroką gamę technik, w tym terapię manualną, terapię szyną zwarciową i zabiegi fizjoterapeutyczne. [18] Jednak leczenie TMD najczęściej jest długie i może wymagać udziału wyspecjalizowanego stomatologa, fizjoterapeuty, chirurga szczękowo-twarzowego i innych specjalistów. [19] Co ważne, TMD często należą do zaburzeń o długotrwałym przebiegu i trudnym leczeniu, stąd mogą wpływać na obniżenie jakości życia pacjentów i ogólne ograniczenie ich funkcjonowania.

Obecnie w diagnostyce TMD wykorzystywane są kryteria International Research Diagnostic Criteria for Temporomandibular Disorders (DC-TMD) [10, 11], które nie obejmują w pełni obiektywnej oceny napięcia i sztywności mięśni żwaczy w przebiegu dysfunkcji narządu żucia. Pomiar napięcia mięśni żwaczy wykonany w oparciu o metodę sonoelastografii fali poprzecznej (shear wave elastography, SWE) wykorzystywany jest w nieinwazyjnej ocenie sztywności tkanek. W metodzie tej fale poprzeczne generowane przez ucisk wykrywane są przez podłużne fale ultradźwiękowe, które przemieszczają się w tkankach znacznie szybciej niż fale poprzeczne. Otrzymany wynik odzwierciedla ilościowy pomiar sztywności tkanki. Do zalet sonoelastografii fali poprzecznej należy niewielka zależność od operatora, wysoka powtarzalność wyniku oraz możliwość ilościowej oceny badanych parametrów. [20, 21] Stąd możliwość wykorzystania pomiaru sztywności mięśni żwaczy w diagnostyce TMD oraz ocenie efektów leczenia tych zaburzeń. [22] Jednakże do tej pory nie przeprowadzono odpowiedniej ilości badań poświęconych tematyce zwiększonej sztywności mięśni żwaczy, a dostępne badania posiadają ograniczenia metodologiczne.

Wprowadzenie badania sonoelastografii fali poprzecznej do pomiaru sztywności mięśni żwaczy u pacjentów z TMD może podnieść jakość obiektywnej diagnostyki i oceny efektów leczenia tych schorzeń, a tym samym stwarza szansę podniesienia jakości opieki stomatologicznej całej populacji. Uzyskanie wiarygodnej metody pomiaru sztywności mięśni żwaczy w przebiegu dysfunkcji narządu żucia ułatwi prowadzenie badań naukowych poprzez możliwość obiektywnego porównania wyników leczenia prowadzonych w różnych ośrodkach z wykorzystaniem różnych metod terapeutycznych. Dodatkowa wartość to otoczenie pacjenta

z TMD interdyscyplinarną opieką z wykorzystaniem najnowocześniejszej nieinwazyjnej metody diagnostyki obrazowej w stomatologii.

IV.CELE PRACY

Celem głównym badania była ocena przydatności sonoelastografii fali poprzecznej w diagnostyce i ocenie efektów leczenia zwiększonej sztywności mięśni żwaczy w przebiegu dysfunkcji narządu żucia. Główny cel pracy został zrealizowany w oparciu o cele szczegółowe:

- 1. Podsumowanie obecnej wiedzy oraz luk w obecnie dostępnych danych naukowych w zakresie wykorzystania sonoelastografii fali poprzecznej w ocenie mięśni żwaczy u osób zdrowych i pacjentów z dysfunkcją narządu żucia. Cel ten został zrealizowany w przeglądzie systematycznym literatury pod tytułem "Great potential of ultrasound elastography for the assessment of the masseter muscle in patients with temporomandibular disorders. A systematic review".
- 2. Określenie wartości referencyjnych sztywności mięśni żwaczy u zdrowych osób dorosłych za pomocą sonoelastografii fali poprzecznej. Cel ten został zrealizowany w publikacji pod tytułem "Determination of reference values of the masseter muscle stiffness in healthy adults using shear wave elastography".
- 3. Ocena sztywności mięśni żwaczy za pomocą sonoelastografii fali poprzecznej u pacjentów poddawanych leczeniu zachowawczemu zaburzeń czynnościowych mięśni żucia oraz ocena skuteczności terapii manualnej wraz z wykorzystaniem szyny zwarciowej w leczeniu pacjentów z dysfunkcją mięśni narządu żucia. Cel ten został zrealizowany w publikacji pod tytułem "Assessment of the masseter stiffness in patients during conservative therapy for masticatory muscle disorders with shear wave elastography".

V. MATERIAŁ I METODY BADAŃ

Badanie kliniczne zostało poprzedzone systematycznym przeglądem literatury poprzedził mającym na celu zebranie i podsumowanie dostępnych dowodów dotyczących stosowania elastografii w ocenie mięśnia żwaczy u osób zdrowych i pacjentów z zaburzeniami mięśni żwaczy, a tym samym zidentyfikowanie luk w obecnej wiedzy. Przegląd

literatury przeprowadzono zgodnie ze standardami Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) – szczegóły znajdują się w publikacji nr 1.

Badanie podzielono na dwa etapy. Celem pierwszego etapu było opracowanie metodyki badania sonoelastograficznego z precyzyjnym określeniem sposobu przyłożenia głowicy i pozycji głowy żuchwy w stawie skroniowo-żuchwowym oraz ustalenie normy sztywności mięśni żwaczy w populacji ludzi zdrowych. Etap ten objął pacjentów bez zaburzeń narządu żucia w wywiadzie i bez odchyleń od normy w badaniu według protokołu DC-TMD. Z tego etapu wyłączono pacjentów leczonych farmakologicznie lekami mogącymi mieć wpływ na napięcie i ból mięśni np. miorelaksanty, SSRI oraz z chorobami ogólnoustrojowymi zwłaszcza neurologicznymi, nowotworowymi, zaburzeniami hormonalnymi, lekami zmieniającymi tonus mięśniowy, pacjentów powyżej 60 r.ż., chorujących na zaburzenia psychiczne i nie wyrażających zgody na udział w badaniu.

Pomiar sztywności mięśni żwaczy wykonywano w oparciu o metodę sonoelastografii fali poprzecznej (shear wave elastography, SWE) stosowanej w nieinwazyjnej ocenie sztywności tkanek miękkich. W metodzie tej fale poprzeczne generowane przez ucisk wykrywane są przez podłużne fale ultradźwiękowe, które przemieszczają się w tkankach znacznie szybciej niż fale poprzeczne. Otrzymany wynik odzwierciedla ilościowy pomiar sztywności tkanki wyrażony w kilopaskalach (kPa). Do zalet tego badania należy niewielka zależność od operatora, wysoka powtarzalność oraz możliwość ilościowej oceny badanych parametrów. Wadą tego badania, że fakt, że każdy organ posiada swoją unikalną charakterystykę i stąd wartości normatywne powinny być ustalane oddzielnie dla każdego z nich. Badanie mięśni żwaczy zostały wykonane przez jednego doświadczonego operatora w takich samych warunkach z użyciem tej samej głowicy i tej samej aparatury. W czasie badania pacjent znajduje się na łóżku w pozycji leżącej na plecach (szczegóły są opisane w publikacji nr 2).

Drugi etap poświęcono ocenie potencjalnej wartości sonoelastografii w ocenie skuteczności efektów leczenia. Kryterium włączenia do grupy badanej była obecność dysfunkcji mięśni narządu żucia wg DC-TMD (grupa II masticatory muscle disorders ze wszystkimi podgrupami). Kryterium wyłączenia stanowiły wcześniejsze leczenie zaburzeń narządu żucia, kryteria farmakologiczne i kliniczne przyjęte jako kryteria wykluczenia w pierwszym etapie badania.

Grupę badaną poddano terapii dysfunkcji narządu żucia z zastosowaniem terapii manualnej i szyny zwarciowej stabilizacyjnej dla żuchwy. Przed rozpoczęciem leczenia oraz

po jego zakończeniu, ocenie poddano: nasilenie dolegliwości bólowych za pomocą skali Numerical Rating Scale (NRS), jakość życia związaną ze stanem zdrowia jamy ustnej (z użyciem wystandaryzowanego międzynarodowego kwestionariusza) oraz kwestionariusze związane z dobrostanem pacjenta (szczegóły podane są w publikacji nr 3). Porównano zmiany wartości sztywności mięśni żwaczy mierzone z użyciem sonoelastografii i wyniki zebrane przez zastosowanie DC-TMD w celu określenia przydatności tej metody w monitorowaniu efektów leczenia.

Badanie było finansowane z środków Narodowego Centrum Nauki (2017/27/N/NZ5/02690). Na przeprowadzenie badania uzyskano zgodę Komisji Bioetycznej przy Uniwersytecie Medycznym we Wrocławiu (KB-592/2018) oraz badanie zarejestrowano w międzynarodowej bazie badań klinicznych clinicaltrials.gov (NCT03844854).

VI.CYKL PUBLIKACJI

 Olchowy A, Wieckiewicz M, Winocur E, Dominiak M, Dekkers I, Łasecki M, Olchowy C. Great potential of ultrasound elastography for the assessment of the masseter muscle in patients with temporomandibular disorders. A systematic review. Dentomaxillofac Radiol. 2020 Dec 1;49(8):20200024. doi: 10.1259/dmfr.20200024. IF: 2,419; MEiN : 100,00

Celem badania było podsumowanie obecnej wiedzy i znalezienie luk w danych dostępnych w literaturze. Cel ten został określony jako podsumowanie obecnej wiedzy na temat wykorzystania sonoelastografii fali poprzecznej w ocenie mięśni żwaczy u osób zdrowych i pacjentów z zaburzeniami mięśni żwacza. Metodą realizacji celu był systematyczny przegląd literatury wykonany w oparciu o obowiązujące wytyczne międzynarodowe dla przeglądów systematycznych (Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines) [PRISMA]. W czasie przeglądu literatury do analizy wybrano 16 spośród wyselekcjonowanych 142 artykułów. W analizowanych artykułach sonoelastografia została wykorzystana w siedmiu badaniach dotyczących mięśni żwaczy. W publikacjach stwierdzono niejednorodność w zakresie protokołów badań, urządzeń, pacjentów, jednostek miary, jak i otrzymanych wyników. Wartości sztywności wykazały korelację między lewym i prawym mięśniem żwaczem u zdrowych osób, ale nie u pacjentów

z zaburzeniami czynnościowymi narządu żucia (TMD). Wartości sztywności były wyższe u pacjentów z TMD, jak również były skorelowane z nasileniem objawów TMD. Badania fantomowe potwierdziły wysoką wiarygodność elastografii.

Na podstawie przeprowadzonego systematycznego przeglądu literatury można stwierdzić, że sonoelastografia fali poprzecznej jest obiecującym narzędziem do oceny sztywności mięśni żwaczy, ale dowody na jej użyteczność kliniczną z dotychczas przeprowadzonych badań są niewystarczające. Należy kontynuować badania na większych grupach, aby określić dokładność elastografii w celu scharakteryzowania zaburzeń mięśni żucia. Otrzymane wyniki dają zatem podstawę do kontynuacji projektu i prowadzenia badań nad sztywnością mięśni żwaczy u osób zdrowych i pacjentów z TMD.

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SYSTEMATIC REVIEW Great potential of ultrasound elastography for the assessment of the masseter muscle in patients with temporomandibular disorders. A systematic review

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Objective: To summarize the available evidence on the use of elastography in the assessment of the masseter muscle in healthy individuals and patients with masseter muscle disorders. Methods: Systematic literature review has been performed according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines.

Results: 16 of 142 studies identified were analyzed. Elastography was used in seven studies. Heterogeneity was observed in terms of study protocols, devices, patients, units of measure, and results. Elasticity values showed a correlation between the left and right masseter muscle side in healthy people, but not in patients with temporomandibular disorders (TMDs). Elasticity values increased in TMD and were correlated with the severity of TMD symptoms. Phantom studies proved the high reliability of elastography.

Conclusion: Elastography is a promising tool for the assessment of the masseter muscle elasticity, but the evidence is insufficient. Studies on larger groups are needed to determine the accuracy of elastography to characterize masticatory muscle disorders.

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Keywords: elastography; elasticity; temporomandibular disorders; masseter muscle; systematic literature review

Introduction

The masseter muscle, being a part of the masticatory apparatus, helps to perform an important physiological function of mastication, which is an initial activity for appropriate digestion. Pathologies of the masseter muscle result in impaired bite force and occlusal morphology, speech disorders, and acute or chronic pain.^{1,2} The assessment of the masticatory muscle is particularly useful for diagnosing and monitoring muscle-related temporomandibular disorders (TMDs), which are frequent orofacial problems. The prevalence of TMD varies greatly across studies. Prevalence of mvofascial TMD was estimated to be 10.5% in United States community females.³ In the Northern Finland Birth Cohort 1966, the prevalence of TMD symptoms reached 34.2% in 46-year-old people and dominated in females.⁴ A Brazilian study conducted in adolescents between the age of 10 and 17 years showed a 33.2% prevalence irrespective of age and economic status.⁵ Studies conducted on the Polish population found that approximately 54% of students presented with TMD

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symptoms.^{6,7} Some other studies suggest that TMD symptoms may be present in up to 40–90% of the population, but without the need for active treatment.⁸ Some reports from the literature link the increase in TMD symptoms to abuse of active substances and poor emotional health status; TMD is diagnosed in over half of the prisoners.^{9,10}

The clinical presentation of TMD includes acute and chronic masticatory muscles and/or temporomandibular joint pain, sounds in temporomandibular joints (clicking and popping), and abnormal jaw movements. The main symptoms may be associated with headache, otolaryngological disorders, and pain within muscles of the neck and shoulder girdle. Physical examination sometimes shows an increased stiffness and tension of the masseter muscles, which is often associated with their hypertrophy, soreness, and pain during palpation. Diagnostic criteria are based on the recommendations of the International Network for Orofacial Pain and Related Disorders Methodology (Diagnostic Criteria for Temporomandibular Disorders; DC-TMD).^{11,12}

Clinical symptoms perceived by patients and the mechanics of the temporomandibular joints are important for the diagnosis of TMD, but they constitute only a part of the picture of the disorders. Novel approaches to evaluate the condition of masticatory muscles may facilitate the diagnosis and enable precise monitoring of the management. One of such techniques is shear wave elastography used for noninvasive assessment of soft tissue hardness. In this method, shear waves generated by pressure are detected by longitudinal ultrasonography waves that propagate in tissues much faster than shear waves. The quantitative measurement of tissue hardness is expressed in kilopascals. The advantages of this method include low dependence on the operator, high repeatability and the possibility of quantitative evaluation of tested parameters.^{13–16} The main disadvantage is that every organ has its unique characteristics, and hence, normative values must be determined for each muscle independently.^{17,18} Currently, although there has been a growing body of evidence, little is known about elasticity values of the masseter muscle as well as the optimal examination

protocol that would enable to obtain repetitive and reliable results.

The goal of this systematic review was to summarize the available evidence on the use of elastography in the assessment of the masseter muscle in healthy individuals and patients with TMD. Authors focused on the techniques and devices used for the assessment of the masseter muscle. Furthermore, the authors aimed at determining the ranges of the masseter muscle elasticity and factors that contribute to its change.

Methods and materials

Evidence acquisition

The databases PubMed. Ovid MEDLINE. Web of Science, and ClinicalTrials.gov were searched for relevant literature on February 19, 2019. The present systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.¹⁹ The search in databases was supplemented with a Google search of grey literature and hand search of the bibliographies of retrieved articles. No restrictions regarding timeframe and geographical scope were applied, but papers published only in English were considered. Electronic search strategies employed the following keywords elastography, shear-wave elastography, sonoelastography, TMD, masticatory, masseter as well as combinations and variations of them and are shown in Supplementary Table 1 to S3. Inclusion and exclusion criteria were defined according to the PICOS (Population, Intervention, Comparison, Outcomes and Study Design) approach (Table 1). Three reviewers performed the literature search. Two reviewers screened records and abstracts and recommended papers for qualitative analysis. The following data were extracted from selected papers: author and year of publication, characteristics of the population under study, examination protocol, the device used, and elasticity values of the normal and diseased masseter muscle.

Table 1 Inclusion and exclusion criteria

PICOS	Inclusion criteria	Exclusion criteria
Population	Healthy patients, phantoms, humans and animals, patients suffering from TMD	Pathologies other than TMD including malignant lesions, benign tumors, injuries
Intervention	Shear-wave elastography or sonoelastography of masseter muscle	-
Comparator	None or any	-
Outcome	Muscle hardness and elasticity	-
Study	RCTs, cohort studies, experimental models, animal models, case reports	Review papers, letters, commentaries, articles not in English

PICOS, Population, Intervention, Comparison, Outcomes and Study Design; RCT, randomized controlled trials;TMD, temporomandibular disorders.

Elastography within masseter muscle Olchowy et al

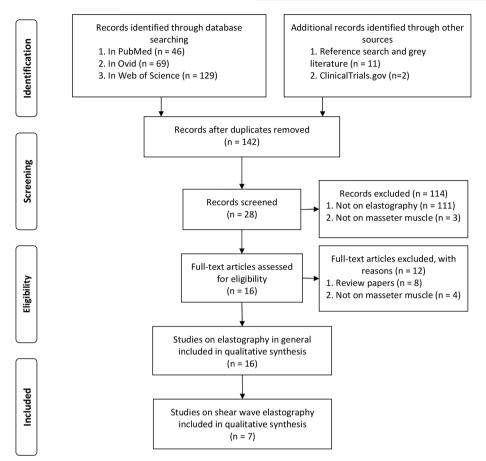


Figure 1 PRISMA flow diagram of the systematic review protocol. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Results

Evidence synthesis

A total of 142 studies were identified, out of which 16 met PICOS criteria and were included in a qualitative analysis of the use of elastography for the assessment of the masseter muscle. For the evaluation of the shear wave elastography values, seven publications were considered. Additionally, two ongoing studies were identified from the Clinical Trials Database. The selection process is shown in the PRISMA flow diagram in Figure 1.

Study populations

A total of 16 studies on 573 subjects were analyzed. These studies included 486 healthy volunteers, 73 patients with TMD, 13 patients who underwent radiotherapy for nasopharyngeal carcinoma (this subgroup was compared to the healthy control group which was of interest in this review; for this reason, the whole study population was included), 1 patient with unilateral temporal myositis, 6 cadavers, and 2 phantoms. Only in two studies, the study groups comprised over 100 participants. Study cohorts were small with a mean number of subjects of 47.7 (median 33.5; range 10–176). The qualitative evaluation of elasticity values focused on studies using shear wave elastography. These studies included 436 (76% of the pooled number of all studies included) subjects with the mean sample size of 72.6 (median 46.5; range 10–176). The characteristics of the 16 studies included are presented in Table 2. The details of studies on shear wave elastography are depicted in Table 3.

Devices used for the measurement of elasticity

Several devices were used to measure elasticity. For strain elastography, two machines were used. In one study, the EUB-7000 device (Hitachi Medical Systems, Tokyo, Japan) equipped with a 6–13 MHz wide bandwidth linear probe was used,²⁸ while four other studies used LOGIQ E9 (GE Healthcare, Tokyo, Japan) equipped with a 4.5–15 MHz wide bandwidth linear active-matrix transducer (ML6-15-D).^{22,23,29,30}

A wide variety of devices were used for shear wave elastography. Supersonic Imaging System Aixplorer ultrasound machine (Aix-en-Provence, France) was used either with a linear-array transducer with a frequency range of 6–13 MHz or 4–15 MHz.^{17,20,25} In two studies, a GE Logic E9 system with a 9 MHz linear

Author	Technique	Study population	Results
Arda, 2011 ²⁰	Shear wave elastography	38 males) with a mean age of 37.7 ± 9.11 years; range, 17–63 years)	The mean elasticity values were 10.4 ± 3.7 kPa for the masseter muscle. The same values in the longitudinal and transverse planes. Values in the longitudinal place were greater in males 10.8 ± 3.9 (range 4–20) than in females 10.3 ± 3.6 (range 2–23) with <i>p</i> value of 0.3. There was no correlation between age and elasticity of the muscle (<i>p</i> = 0.50).
Ariji, 2009 ²¹	Real-time sonographic elastography	14 healthy volunteers (10 males and six females) and two female patients with TMD	The mean MSI of the right and left muscles in the healthy volunteers were 0.85 ± 0.44 and 0.74 ± 0.35 . There was a significant correlation between the right and left MSI ($R = 0.67$, $p < 0.001$). The mean MSI was lower in males and in females (0.64 ± 0.34 and 1.05 ± 0.35 ; $p = 0.008$). MSI values of a 29-year-old female with TMD of the right masseter muscle were 2.06 for the right and 0.43 for the left masseter muscle. MSI values of a 46-year-old female with bilateral TMD were right 3.71 for the right and 0.22 for the left masseter muscle.
Ariji, 2012	Strain sonoelastography	35 healthy volunteers (20 males and 15 females) with a mean age of 41.4 ± 12.4 years; range, 25–65 years)	MEI was comparable for both masseter muscles with values of 0.79 \pm 0.43 for the right side-and 0.74 \pm 0.37 for the left side ($p = 0.5737$). A strong correlation was observed between the two sides ($R = 0.7739$; $p < 0.001$).
		8 TMD patients (2 males and six females) with unilateral myofascial pain with a mean age of 44.1 ± 9.6 years; range, $32-60$ years)	MEI was higher for the symptomatic side-than for the contralateral side (1.13 \pm 0.43 vs 0.77 \pm 0.31; <i>p</i> = 0.03). The correlation between the two sides was insignificant (<i>R</i> = 0.4741; <i>p</i> = 0.2050).
Ariji, 2013 ²²	Strain sonoelastography	ten healthy volunteers (8 males and two females) with a mean age of 40.9 ± 12.4 years; range, 26–54 years	MEI was comparable for both masseter muscles with values of 0.84 ± 0.21 for the right side-and 0.85 ± 0.21 for the left side. MEI increased significantly after exercise.
Ariji, 2016 ²³	Strain sonoelastography	37 TMD patients with myofascial pain (6 males and 31 females) with a median age of 45 years (range 9–83 years)	MEI was calculated at baseline and after 9.5 weeks of massage therapy. Patient were divided by response to the therapy. MEI in the therapy-effective was 1.33 at the baseline, 1.17 after the third treatment session, and 1.00 after the last treatment session. In the therapy-ineffective group, MEI were 1.20, 1.08, and 1.08, respectively. In the first group, values after the treatment were significantly lower in comparison to baseline, while in the second one, the differences were insignificant.
Ariji, 2016 ²³	Strain and shear wave elastography	Phantoms and 30 healthy volunteers (21 males and nine females) with the median age of 31.5 years; range, 26–63 years	In healthy subjects, the average hardness on shear- wave sonoelastography was 42.82 ± 5.56 kPa at rest and 53.86 ± 8.26 kPa during jaw clenching. Differences between the left and right hardness values and between males and females were insignificant.
Badea, 2014 ²⁴	Shear wave elastography	25 healthy controls and 13 patients who had had radiotherapy for nasopharyngeal carcinoma (35 Gy minimum)	Shear waves velocities were measured in m/s. The values for relaxation and contraction in controls and patients presented no differences $(1.79 \pm 0.52 \text{ vs} 1.72 \pm 0.73; p = 0.72 \text{ and } 1.70 \pm 0.48 \text{ vs} 1.59 \pm 0.77; p = 0.98)$. Differences between groups were insignificant $(1.79 \pm 0.52 \text{ vs} 1.65 \pm 0.63; p = 0.78)$.
Damian, 2016	Strain elastography	One case report of unilateral temporal myositis	Values not available.
Ewertsen, 2018 ¹⁸	Shear wave elastography	1 2	The mean shear wave speed in the parallel plane was 2.45 \pm 0.25 m/s. The effect of sequence (day-to-day variation) and dominant side-were insignificant. The effect of scan plane in relation to muscle pennation was statistically significant.

 Table 2
 Characteristics of the studies included in the systematic review

(Continued)

Table 2 (Continued)

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Author	Technique	Study population	Results
Gotoh,2013	Strain elastography	10 healthy volunteers (8 males and 2 females) before, immediately after, and 10 min after static contraction	The EI ratios of the right and left masseter muscles were 0.84 ± 0.21 and 0.85 ± 0.21 , respectively, before exercise, 1.75 ± 0.43 and 1.71 ± 0.43 immediately after exercise, and 0.90 ± 0.38 and 0.87 ± 0.36 10 min after exercise. There were no significant differences between the right and left EI ratios in any of the phases. The EI ratios immediately after exercise were significantly higher than those before exercise and 10 min after exercise on both right and left sides.
Herman, 2017 ¹⁷	Shear wave elastography	176 volunteers with no known history of head and neck disease with a mean age of 48.8 years and range from 21 to 91 years.	The mean stiffness was 10.0 ± 4.3 kPa. A small increase with age was observed. BMI and weight had small effect on stiffness values.
Joy, 2015 ²⁵	Shear wave elastography	6 Thiel soft-embalmed human cadavers (3 males and 3 females) with a mean age at death of 81.3 ± 13.2 and range from 63 to 97 years.	Masseter 15.0 (95% CI: 6.3–35.5) kPa Sex, age at death and repeated measurements had no effect on elasticity.
Nakayama, 2015 ²⁶	Strain elastography	 Phantoms with elasticity of 20, 40 and 60 kPa. 25 healthy volunteers (10 females and 15 males) with a mean age of 30.8 ± 9.8 years and range from 20 to 53 years. 	No differences in EI ratios between males and females as well as between the right and left sides were observed. EI ration increased during clenching. Less variations were observed for the hard coupling agent. The EI ratios increased and showed wide variation with clenching.
Takashima, 2017 ²⁷	Shear wave elastography	26 females with bilateral masseter muscle pain who were classified as having TMD Ia (myofascial pain; n = 13) or Ib (myofascial pain with limited opening; $n = 13$) and healthy controls consisted of 24 females. Age range of TMD patients was 15 to 46 years, while controls 23–45 years.	TMD Ia = 1.96 m/s (12.5 kPa) TMD Ib = 2.00 m/s (13.0 kPa) Healthy females = 1.27 m/s (5.25 kPa)Stiffness was significantly greater in TMD patients ($p < 0.05$). It was positively correlated with pain ($p < 0.05$) and negatively with maximum assisted mouth opening ($p < 0.05$) and painless mouth opening ($p < 0.05$).

MEI, masseter muscle elasticity index calculated as the value of (the mean elasticity index of the masseter muscle)/(the mean elasticity index of the subcutaneous fat tissue) and was defined as the total hardness; MSI, masseter stiffness index defined as the ratio of elasticity of the fat tissues and elasticity of the masseter muscle; TMD, temporomandibular disorders; EI, elasticity index defined as the strain values of each area compared with the average strain value of the whole area of interest; EI ratio was calculated as the mean EI of scoring area divided by the mean EI of background.

array transducer was used.^{18,21} Ariji et al used a coupling agent with Young's modulus of 40 kPa on the surface of the masseter muscle as the reference and presented the results in kPa.²¹ Another two studies were conducted using the ACUSON (S2000 or S20001) device (Siemens AG, Munich, Germany) with an 8–14 MHz linear transducer.^{24,27}

The devices used in the studies for shear wave elastography are listed in Table 3.

Techniques used for the measurement of elasticity in masseter muscles

The masseter muscle was examined in two positions: supine or sitting position; the supine position was more frequently used for shear wave elastography, whereas the sitting position was used for strain elastography. Slight differences were noted across the studies when comparing the technique of scanning.

In the early study on masseter muscle elasticity conducted by a team from Japan, the patient was seated in an upright position with the head in the natural position. The measurements were acquired parallel to the anterior border of the muscle. The probe was placed 15 mm, or 20 mm in more recent studies, above the lower margin of the mandible. In patients with tender points in the masseter muscle, the points were included in the area scanned.^{22,28} In the study conducted by Ewerstsen et al, the patient was examined when sitting on a chair while the sonographer was sitting behind the patient. The recordings were performed after light pre-compression of the skin.¹⁸ Takashima et al who used the sitting position during examination evaluated three points (anterior border, center, and posterior border) of the masseter muscle body.²⁷ Gotoh et al examined their patients in an upright position with the head in the natural position. They used a multiple focus technique with a focal range of 0.5–2.0 cm and image depth of 4.0 cm. Elasticity was measured 15 mm above the edge of the mandible.³⁰

In both studies from 2016 performed by Ariji's group, the patient lied in the supine position, but the head of the transducer was applied in the same manner. For better accuracy, each of the measurements was performed twice, and the results were averaged.^{21,23} The supine position dominated in studies using shear wave

Table 3	Characteristics of studies on shear wave elastography
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Author	Device	Patients positioning	Study population	Elasticity values of the masseter muscle
Arda, 201 1 ²⁰	Supersonic with a linear-array transducer with a frequency range of 6–13 MHz (Aix-en-Provence)	Patient in a supine position	127 healthy volunteers	Total: 10.4 ± 3.7 kPa (range, 2–23) Males: 10.8 ± 3.9 kPa (4-20) Females: 10.3 ± 3.6 kPa (2-23)
Ariji, 2016 ²³	Logic E9 with a 9 MHz linear array transducer; the coupling agent with Young's modulus of 40 kPa was used (GE Healthcare)	Patient in a supine position	30 healthy volunteers	At rest 42.82 ± 5.56 kPa At jaw clenching 53.86 ± 8.26 kPa
Badea, 2014 ²⁴	ACUSON S2000 with an 8–14 MHz linear transducer; ARFI mode (Siemens)	Patients in a supine position with the head half extended	25 healthy volunteers and 13 patients after radiotherapy	Central measurement – m/s Healthy at rest; right 1.87 \pm 0.52 and left 1.6 \pm 0.47 Healthy at contraction right 1.57 \pm 0.54 and left 1.47 \pm 0.53 Patients at rest; right 1.67 \pm 0.6 and left 1.6 \pm 0.34 Patients at contraction right 1.41 \pm 0.52 and left 1.68 \pm 0.9
Ewertsen, 2018 ¹⁸	Logic E9 system with a 9 MHz linear array transducer (GE Healthcare)	Patient in a sitting position	10 healthy volunteers	2.45 ± 0.25 m/s
Herman, 2017 ¹⁷	Supersonic with a compact linear array transducer SL 15–4 (4–15 MHz) (Aix-en-Provence)	Patient in a supine position	176 healthy volunteers	10.0 ± 4.3 kPa, median 9.85 kPa;
Joy, 2015 ²⁵	Supersonic with a with a frequency range of 4–15 MHz (Aix-en-Provence)	Cadavers in a supine position	Six cadavers	15.0 (95% CI: 6.3–35.5) kPa
Takashima, 2017 ²⁷	ACUSON S2001 with an 8–14 MHz linear transducer (Siemens)	Patient in a sitting position	26 females with TMD and 24 healthy females	TMD Ia = 1.96 m/s (12.5 kPa) TMD Ib = 2.00 m/s (13.0 kPa) Healthy females = 1.27 m/s (5.25 kPa)

TMD, temporomandibular disorders.

elastography.^{17,20,24-26} Additionally, Badea et al examined patients in a supine position with the head half extended and advised to refrain from swallowing during the examination. Nakayama et al instructed the patients to turn the head so that the side to be examined faced upwards and to relax the masseter muscle.²⁶ Regarding contraction during the examination, Nakayama et al asked the patients to clench the mandible with the maximum force, while Badea et al asked the patients to make a moderate contraction.^{24,26}

Most studies used some ultrasound gel on the skin over the muscle and carried out scanning without compressing the tissue.^{17,20,25,27}

Elasticity values of the masseter muscle

Two studies showed that the elasticity of the masseter muscle differs significantly not only from that of different organs but also from that of different muscles. Arda et al²⁰ compared elasticity values in different locations of the body and found a significant difference between them in healthy people. The lowest values were recorded in the spleen $(2.9 \pm 1.8 \text{ kPa})$ and the highest in the Achilles tendons (51.5 ± 25.1 kPa). Moreover, considerable differences were noted between the same tissues, but with different locations and functions, *e.g.* elasticity

for the masseter muscle was 10.4 ± 3.7 kPa, while for the supraspinatus muscle, it was three times higher and reached 31.2 ± 13 kPa.²⁰ Herman et al reported a difference in elasticity across different organs; however, the difference between the sternocleidomastoid muscle (9.89 \pm 4.1 kPa) and the masseter muscle (10.04 \pm 4.3 kPa) was small.¹⁷

Overall, in studies on humans, four studies expressed elasticity values of the normal masseter muscle in kPa^{17,20,21,27} while three studies used velocity (m/s) to report elasticity.^{15,20,25} Additionally, one study on cadavers reported elasticity in kPa.²⁵

For kPa, the values at rest in healthy people ranged from 5.25kPa in the study by Takashima et al²⁷ to 42.82 \pm 5.56kPa in the study by Ariji et al.²¹ It is worth noting that the studies were conducted using different devices and coupling agents. The study by Arda et al²⁰ and Herman et al¹⁷ showed similar results (10.4 \pm 3.7 and 10.0 \pm 4.3kPa). Both research teams used the Supersonic device. Only one study reported values of 12.5–13kPa for patients with TMD.²⁷

For m/s, the values at rest in healthy people ranged from 1.27 m/s in the study by Takashima et al²⁷ to 2.45 m/s in the study by Ewertsen et al.¹⁸ Of these studies, two were conducted using ACUSON Siemens devices but with different models, and one study used Logic E9 from GE Healthcare.

The values of elasticity of the masseter muscle are presented in Table 2.

Factors affecting elasticity values of the masseter muscle The impact of age remains unclear. One study found no correlation between age and elasticity of the muscle,²⁰ while another study noted a small increase in elasticity with age.¹⁷ Regarding sex, three studies reported no differences in elasticity between males and females.^{20,25,26} Only one study reported significantly lower values of the masseter stiffness index in males than in females.²⁸ Some studies investigated whether there are differences between both masseter muscles. In most cases, a significant correlation between the right and left masseter stiffness index in healthy volunteers was observed, indicating that elasticity of both normal muscles is similar.^{21,22,26,28-30} Differences between the sides of masseter muscles appeared for pathologies. In patients with TMD, the masseter muscle elasticity index was higher for the symptomatic side than for the contralateral side.^{22,28} More detailed report by Takashima et al showed significantly increased stiffness in patients with TMD as well as a positive correlation of stiffness with pain and a negative correlation with maximum assisted mouth opening and painless mouth opening.²⁷ The history of radiotherapy did not affect elasticity values. Exercise increased the masseter muscle elasticity index.²⁹ The effect of contraction or clenching is not clear because of conflicting results.^{21,24,26}

Discussion

The present systematic review shows small evidence for the use of elastography to assess the masseter muscle. Reports available in the literature are heterogeneous because the studies were conducted using different devices, protocols, and health conditions of patients. Additionally, they report results of elastography with different units, which cannot be compared directly.

The main limitation of this review is the small number of studies included in the qualitative evaluation of elastography of the masseter muscle. Large heterogeneity across the studies precluded not only determining normative values but also comparing elasticity values in different pathologies. Because of the sparsity of data, also studies on cadavers and phantoms were included to show the background of the use of elastography as well as to capture all possible evidence in this scope. Joy et al²⁵ used Thiel embalmed cadavers which are used for medical research as this method preserves greater flexibility compared to formalin-embalmed cadavers. In the phantom study, a muscle phantom of known elasticity was used and compared to sonographic results obtained from the measurement of healthy volunteers.²⁶ This study proved that on one hand, measurements are reliable and on the other, that can be used to measure tissue hardness in humans. Due to the heterogeneity of the studies, authors were unable to conduct a metaanalysis on the change in the masseter muscle elasticity between healthy people and patients with TMD.

Different measures of elasticity were used across studies. Masseter muscle elasticity index and elasticity index as well as masseter stiffness index (MSI) are defined in Table 2; they were used for strain sonoelastography and real-time sonographic elastography. The results of shear wave elastography were presented in two units m/s and kPa. These two units represent a different approach to measurement; m/s shows the shear wave speed with which the waves propagate in a given tissue, while kPa is calculated from the velocity of the shear waves using Young's elastic modulus. Because the retrospective calculation of kPa from m/s and vice versa³¹ is not feasible, authors recommend providing results using either kPa or both units.

The studies included in the present review analyzed several factors that were important for the assessment of masseter muscles in patients diagnosed with TMD. First, a correlation between the left and right sides of the masseter muscle was confirmed for healthy people. Second, the masseter muscle affected by TMD presented with increased values of elasticity. Furthermore, elasticity values correlated with the severity of TMD symptoms. Finally, a strong correlation between actual and measured hardness confirmed by phantom studies proves the high reliability of elastography. The noninvasive nature of this examination and real-time display of results increase its potential to be accepted by patients. All these features suggest that elastography has the potential of being a valuable tool for the assessment of muscle-related TMD and monitoring the results of the management.

The European Society of Radiology highlights the need for the development of new imaging biomarkers that have sufficiently high accuracy and reproducibility in detecting pathological processes.³² From the European Society of Radiology perspective, elastography still requires to be standardized and validated by gathering evidence from large studies. Currently, two ongoing studies are in progress and have been registered at ClinicalTrials.gov. Both studies aim to assess shear wave elastography. The first study will enroll 20 participants,³¹ while the second will enroll 150 participants³³ and is focused on determining elasticity values in patients with TMD and healthy subjects. In authors institution, attempts have been made to gain experience in using shear wave elastography to examine the masseter muscle. An example of a shear wave image of the masseter muscle of a healthy person is shown in Figure 2. New studies are showing a growing interest in this modality with the aim to improve oral health in patients with TMD.

Currently, there is no reliable method for the assessment of the masseter muscle in patients with TMD.



Figure 2 Image shows shear wave elastography of the masseter muscle of healthy volunteer (33-year-old male). Ultrasound linear probe was placed longitudinally to the long axis of the muscle and the presented image was obtained. Three ROIs of 3 mm in diameter each were placed in the central aspect of the muscle belly and provided three independent measurements. The mean elasticity of the masseter muscle calculated from 3 measurements was 9.4 kPa.

However, several attempts have been made and investigated in clinical trials. The use of diffusion-weighted MRI showed that it could be useful to evaluate myalgia of the masticatory muscles.³⁴ Electromyography is another method which can help to make a proper diagnosis, exclude other pathologies and measure the severity of pain.³⁴ It is worth noting that TMD is a complex condition in which an interplay of several factors and overlap of other conditions can be observed. Complete assessment of the patient requires checking the conditions of temporomandibular joint which can be done with ultrasound³⁵ or magnetic resonance.³⁶

Conclusion

Elastography is a promising tool for the assessment of the masseter muscle elasticity for improved diagnosis of

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Opublikowane dotad badania wskazują, że sonoelastografia jest obiektywną i wiarygodną metodą oceny mięśni i narządów wewnętrznych, jednak każdy organ ma swoją własną charakterystykę sztywności i dlatego wymaga indywidualnych wartości odniesienia. Skąd konieczność ustalenia wartości referencyjnych dla mięśni żwaczy. Celem niniejszego badania było określenie wartości referencyjnych sztywności mięśni żwaczy u zdrowych osób dorosłych za pomocą sonoelastografii. W badaniu przeanalizowano dane 140 zdrowych ochotników (74 meżczyzn, 66 kobiet) z medianą wieku 50 lat. Zgodnie z otrzymanymi wynikami, ogólna średnia sztywność wyniosła $10,67 \pm 1,77$ kPa. Średnie wartości były niższe o 2,25 kPa (9,15%) u kobiet w porównaniu z mężczyznami (9,48 ± 1,47 kPa vs 11,73 ± 1,27 kPa; p < 0,0001). Wartości sztywności wzrastały wraz z wiekiem, przy współczynniku korelacji około 0,35 i p < 0,0001. Wiek był istotnym czynnikiem wpływającym na sztywność mięśni żwaczy. Wartości sztywności lewego i prawego mięśnia żwacza były podobne. Podanie pozwoliło na wyciągnięcie kilku istotnych wniosków. Wartości sztywności są znacznie niższe u kobiet niż u mężczyzn z różnicą wynoszącą 9%. Wiek istotnie wpływa na sztywność mięśni żwaczy, a wartości sztywność znacznie wzrastają wraz z wiekiem, szczególnie u mężczyzn. Niezbędne są jednak dalsze badania w celu określenia dokładnych zakresów sztywności uwzględniających wiek i płeć u osób zdrowych oraz u osób z zaburzeniami i różnymi stanami patologicznym w obrębie narządu żucia.





Article Determination of Reference Values of the Masseter Muscle Stiffness in Healthy Adults Using Shear Wave Elastography

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Abstract: Shear wave elastography (SWE) is an objective and reliable method for the assessment of muscles and internal organs. Every organ exhibits its own stiffness characteristics and hence requires individual reference values. We aimed to determine the reference values of stiffness of the masseter muscle in healthy adult individuals using SWE. We analyzed the data of 140 participants (74 men, 66 women) with a median age of 50 years. The overall mean elasticity was 10.67 ± 1.77 kPa. The average values were lower by 2.25 kPa (9.15%) in women compared to men (9.48 \pm 1.47 kPa vs. 11.73 \pm 1.27 kPa; *p* < 0.0001). The values of stiffness increased with age, with a correlation coefficient of about 0.35 and a *p* < 0.0001. Age was a significant influencing factor of masseter muscle stiffness. The left and right masseters had similar stiffness. We conclude that stiffness values are significantly lower in women than in men with a difference of 9%. Age significantly influences the stiffness of masseter muscle, and the values of stiffness increase significantly with age, particularly in men. However, further studies are required to determine the precise ranges of stiffness accounting for age and sex in healthy subjects and people with disorders and conditions of the masticatory system.

Keywords: masseter muscle; masticatory system; normal values; reference values; shear wave elastography

1. Introduction

Up to date, several ultrasound elastography techniques have been used for the evaluation of muscle stiffness. These include transient elastography, acoustic radiation force impulse elastography, real-time tissue elastography, and real-time shear wave elastography (SWE). Although SWE has been recently introduced to clinical practice, it has been validated and is gaining attention among practitioners. An SWE device produces mechanical vibration sources which radiate low-frequency shear waves inside tissues, creating two intense plane shear waves [1]. These waves propagate through soft tissues, promoting their distortion adequately to their degree of stiffness. Then, the waves are registered by an ultrafast scanner. SWE allows determining the actual elastic modulus of tissues and recording the stiffness (in kPa) of the region of interest (ROI) in an organ. The technique is reproducible, operator independent, and quantitative [2]. An SWE device is integrated into an ultrasound system with standard ultrasound probes. Hence, SWE can be carried out as part of an additional routine examination or during a standard examination.

Clinical applications of SWE primarily include the evaluation of muscles and internal organs. However, every organ exhibits its own stiffness characteristics and therefore requires individual reference values. The reference values for muscles have been mainly established for healthy people. Ewertsen et al. [3] determined the reference values for neck and shoulder muscles; Wang et al. [4] attempted to determine the reference ranges of stiffness for the upper trapezius during different degrees of shoulder abduction; Lallemant-Dudek et al. [5] aimed to define the reference values for healthy muscles and muscles affected by spastic cerebral palsy. Their study focused on the long head of the biceps brachii



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Copyright: © 2021 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (https:// creativecommons.org/licenses/by/ 4.0/). and medial gastrocnemius. Regarding internal organs, the values for the liver and breasts have been well established for both healthy people and people presenting pathologic conditions [6,7]. In many diseases (e.g., breast cancer), SWE helps to make a diagnosis, determining the stage of the disease, and evaluating the response to treatment [8].

Taking into account the characteristics of SWE, we decided to use it for the assessment of the masticatory muscles. Patients with temporomandibular disorders (TMD) often suffer from hypertrophy and increased tension of the masseter muscle [9,10]; however, hypertrophy is not always associated with TMD and its etiology remains unexplained. These symptoms can be monitored by SWE, and the response to treatment can be evaluated [11]. Furthermore, SWE can be used to assess the condition of the masseter muscle by a trained dentist during check-up visits [12]. For this reason, we attempted to establish the reference values for a normal masseter muscle tissue in healthy adult individuals, which can help to differentiate any disorders and conditions, using SWE. Additionally, we investigated the reference values in terms of age and gender, which are factors affecting the stiffness of the masseter muscle.

2. Materials and Methods

We enrolled a total of 140 healthy adult volunteers (164 volunteered for this study and 140 were included based on the inclusion criteria). The percentage of excluded subjects was lower than in the general population [13] because we aimed to recruit only healthy people. Inclusion criteria for the study were as follows: age of 18 years or older, absence of any signs and symptoms suggestive of TMD according to the Diagnostic Criteria for Temporomandibular Disorders [14] protocol, and no previous diagnosis of TMD or treatment for this condition. People with neuromuscular disorders and/or rheumatoid disease, cancer, or inflammation in the facial region, pregnant and breastfeeding women, and those using muscle relaxants and/or other drugs that can alter the functioning of muscles were excluded. In addition, individuals with any abnormalities within the masticatory muscles, such as pain within the masseter and parafunctional oral habits, were not included. All participants took part in the study voluntarily and gave informed consent. The study was conducted according to the Declaration of Helsinki and was approved by the Bioethical Committee at Wroclaw Medical University (KB–592/2018).

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During the study, each participant was first interviewed by a trained dentist and examined for the fulfillment of the inclusion criteria. If qualified for the study, the participant was referred for the SWE examination. All the SWE assessments were conducted by a single trained radiologist with seven years of experience in the technique. For each participant, three measurements each were taken in the right and left masseter muscle and averaged. In the previous pilot phase (unpublished data), measurements were made with a transducer placed longitudinally and transversely to the masseter muscle; however, no significant differences were found between measurements. Based on our experience, we recommend a longitudinal (parallel) placement as shown in Figure 1. In our opinion, such placement is more intuitive. Additionally, it is easier to achieve a 0° angle than a 90° angle of the probe in relation to muscle fibers. A similar approach was used by Chang et al. for measurement of the middle part of the masseter muscle [15]. While taking the measurement, the probe was placed parallel to the longitudinal axis of the masseter muscle in the widest part (the midpoint level) of the muscle in the belly. The middle part of the masseter muscle was identified while the patient clenched his/her teeth on the most protruding part of the muscle.

A circular, 4 mm ROI was positioned in the center of the muscle tissue. The ROI of 4 mm was chosen to reflect the size of the masseter, avoiding the deep and superficial fascia of the muscles. It was located in an area of relatively uniform elasticity as guided by an SWE image and standard deviation (SD) of less than 30% of the mean elasticity

value. During the SWE examination, the patients were asked to lie in a supine position, remain relaxed and comfortable, and refrain from swallowing. Before the examination, the probe was covered with an ultrasound gel to reduce the passage of air between the probe and the skin, which enabled good visualization. The tissues were not compressed during the examination.

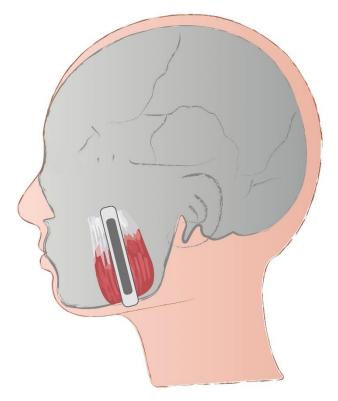


Figure 1. Placement of the probe on the masseter muscle during shear wave elastography examination.

The stiffness of the masseter muscle was measured with the Aixplorer Ultimate device (SuperSonic Imagine, Aix-en-Provence, France) using a high-frequency linear probe SL 18-5 (5–18 MHz). The obtained measurements were validated using the elasticity QA Phantom model 049A (Computerized Imaging Reference Systems, Inc, Norfolk, VA, USA).

Data were statistically analyzed using MedCalc v. 19.5.3 (MedCalc Software Ltd., Ostend, Belgium). Means and SDs were calculated. The Shapiro–Wilk test was used to analyze the data distribution. The hypothesis of normal distribution was rejected for all variables. The stiffness values were compared using the Mann–Whitney U test. Correlations between age and stiffness were checked with Spearman's rank correlation coefficient. Regression models were built for predicting the stiffness value of the masseter based on age. A probability value lower than 0.05 was considered statistically significant.

3. Results

We analyzed data obtained from 140 healthy volunteers (74 men and 66 women) with a median age of 50 years (95% confidence interval (CI): 45.9–55). For women, the median age was 45 years (95% CI: 40–53) with a range from 22 to 65 years. Men were older with a median age of 54 years (95% CI: 47–57.9) and a range from 25 to 65 years. The age distribution is shown in Figure 2. The mean elasticity of all measurements was 10.67 ± 1.77 kPa. The values of stiffness by sex and side of the body are presented in Table 1. Figure 3 shows typical SWE images.

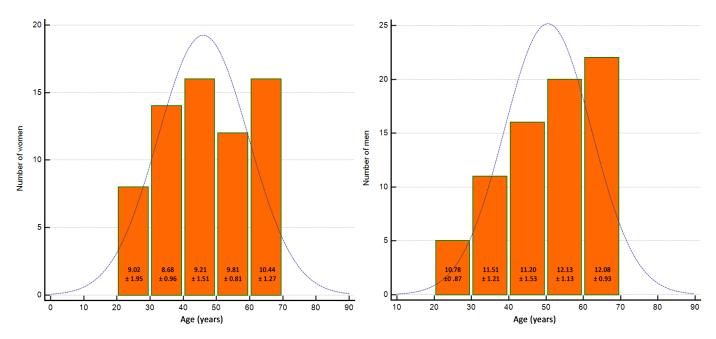


Figure 2. Age distribution in the study group by gender with a stiffness means expressed in kPa for age range.

Table 1. Values of stiffness in the study group.

	Mean \pm SD, kPa	Difference, kPa (%)	<i>p</i> -Value
Men (<i>n</i> = 148) Women (<i>n</i> = 132)	$\begin{array}{c} 11.73 \pm 1.27 \\ 9.48 \pm 1.47 \end{array}$	2.25 (9.15%)	<0.0001
Left total ($n = 140$) Right total ($n = 140$)	$\begin{array}{c} 10.66 \pm 1.76 \\ 10.67 \pm 1.78 \end{array}$	0.01 (0.09%)	0.9706
Women aged < Me Women aged > Me	$8.8 \pm 1.4 \\ 10.16 \pm 1.25$	1.36 (13.4%)	0.0001
Men aged < Me Men aged > Me	$\begin{array}{c} 11.43 \pm 1.44 \\ 12.03 \pm 1.01 \end{array}$	0.6 (4.9%)	0.0661

Abbreviations: Me, median; *n*, number of patietns, SD, standard deviation.

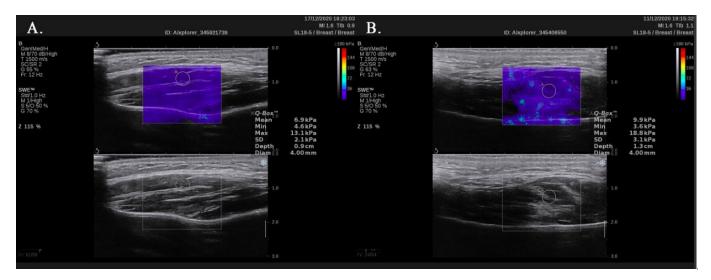


Figure 3. Shear wave elastography images of the masseter muscle of healthy volunteers: a 22-year-old woman (**A**) and 28-year-old man (**B**).

We investigated the relationship between age and stiffness values of the masseter muscle. Taking into account the side of the body, a moderate correlation was found between age and the stiffness value of the left masseter muscle (r = 0.353, 95% CI: 0.199–0.490, p < 0.0001). Similarly, a moderate correlation was found between age and the stiffness value of the right masseter muscle (r = 0.346, 95% CI: 0.192–0.485, p < 0.0001). As the comparison between left and right masseter muscle did not show any significant difference, we analyzed the stiffness values of left and right masseter together to calculate the correlation coefficients by sex. In women, a moderate correlation was found between age and the stiffness of the masseter muscle (r = 0.449, 95% CI: 0.232–0.623, p = 0.0002). On the other hand, a weak correlation was found in the case of men (r = 0.265, 95% CI: 0.0384–0.465, p = 0.0227).

Regression models were built for predicting the stiffness value of the masseter based on age separately for men and women. In each model, the stiffness values were set as a dependent variable (Y), and age as an independent variable (X). For women, the regression equation was as follows: $y = 7.3351 + 0.04663 \times x$. The average stiffness value regardless of age was 7.33 kPa, which increased by 0.05 kPa for every additional year. Age significantly influenced the stiffness values (p < 0.0001). The unadjusted *R*-squared was calculated as 0.1870, and the model thus explained approximately 18% of the variability. For men, the regression equation was as follows: $y = 10.2745 + 0.02881 \times x$. The average stiffness value regardless of age was 10.27 kPa, which increased by 0.03 kPa for every additional year. Similar to women, age significantly influenced the masseter muscle stiffness in men (p < 0.0001). The unadjusted *R*-squared was 0.0709, and the model thus explained approximately 7% of the variability.

4. Discussion

The reference values of the masseter muscle stiffness have not been established so far in the literature. Our study showed that the mean stiffness value in men was 11.73 ± 1.27 kPa, and in women was 9.48 ± 1.47 kPa. Age and sex had a significant impact on muscle stiffness. The average stiffness values were lower by 2.25 kPa (9.15%) in women compared to men. The values increased with age with a correlation coefficient of about 0.35 and a *p*-value below 0.0001. Thus, age was identified as a significant influencing factor of masseter muscle stiffness.

SWE is gaining importance in oral and facial imaging. Despite the insufficient evidence for its use in determining the stiffness of masticatory muscle, SWE has been widely applied over the past few years. However, there is still a need for large studies to establish the reference values of stiffness. For this reason, we conducted this study on 140 healthy adult individuals using SWE. Few reports providing stiffness values can be found in the literature [16]. Nevertheless, some factors can affect the results, which include the method used, equipment, age, sex, concomitant diseases, medications, and the degree of muscle tension. In Table 2, we summarize the results of previous research on masticatory muscle stiffness in healthy subjects with measurements taken using the Aixplorer device. It can be noted that the mean stiffness values range from 10.0 to 11.46 kPa. We used the same device in the present study and also expressed the results in kPa for better comparison with previous results, given that stiffness measured with different devices can produce different values [16]. In the Aixplorer device, SWE is performed using SuperSonic shear imaging. This means that acoustic radiation force induces displacement in the examined tissues and generates perpendicularly propagating shear waves. Next, those shear waves are detected by longitudinal ultrasonography waves that propagate faster than shear waves. The Aixplorer device provides quantitative real-time mapping of elastic modulus across soft tissue and objective stiffness value for the ROI expressed in kPa [1]. This method is characterized by low dependence on the operator, high repeatability, and the provision of quantitative assessment; however, a training and learning curve is required to use SWE.

Author	Quantity	Elasticity Values of the Masseter Muscle, kPa
		Total: 10.4 \pm 3.7 (range, 2–23)
Arda, 2011 [2]	127 healthy adult volunteers	Men: 10.8 ± 3.9 (range, 4–20)
		Women: 10.3 ± 3.6 (range, 2–23)
Herman, 2017 [17]	176 healthy adult volunteers	10.0 ± 4.3 , median 9.85
Olchowy, 2020 [11]	20 healthy adult volunteers	11.46 ± 1.55
Oleboury 2021 [12]	E1 healthy adult value toors	Left: from 10.72 \pm 2.32 to 10.67 \pm 2.23
Olchowy, 2021 [12]	51 healthy adult volunteers	Right: from 10.88 ± 2.34 to 10.54 ± 2.38
		Total: median 11.35 (interquartile range, 9.7–12.65)
Olchowy, 2021 [18]	40 healthy adult volunteers	Left: 10.99 ± 2.04
	-	Right: 11.01 ± 2.21

Table 2. Values of masseter muscle (expressed in kPa) stiffness from previous studies measured with the Aixplorer device.

Reports from the literature regarding the relationship between the stiffness of the masseter muscle and age are inconclusive. Some researchers report a positive correlation [19,20] and some report a negative one [21,22], whereas some claim that the stiffness values do not depend on age [2,23]. Our study revealed a significant correlation between the stiffness of the masseter muscle and age, with a correlation coefficient of 0.265–0.449. Thus, it can be interpreted that the stiffness of the masseter muscle age.

The effect of age on stiffness has been reported in the literature for other muscles but not for the masseter muscle. Ekby et al. [18] examined the stiffness of biceps brachii in a group of 133 healthy subjects and reported similar findings to our study. They found that shear modulus values increased with age in full extension of the muscle, especially in people over 60 years of age. A possible explanation for increased stiffness at an older age is sarcopenia—a condition characterized by the loss of muscle mass and strength which is associated with increased collagen content in muscles [20,24]

On the other hand, Alfuraih et al. [21] reported contrasting results. They measured the stiffness of the quadriceps and biceps brachii in 77 healthy participants who were divided into three cohorts: young (20–35 years), middle aged (40–55 years), and elderly (above 75 years). Their results show a gradual decrease in resting muscle stiffness with a significant decline in the oldest group—the stiffness was 16.5% lower in the elderly participants compared to the young participants. They also revealed that sex and body mass index did not have any effect on muscle stiffness. Yoshida et al. [23] reported that the stiffness of gastrocnemius muscle was 9% lower in participants under 30 years of age than in those aged 30 years and older with a *p*-value of < 0.001, but they also found that the correlation between age and stiffness was not significant (r = 0.173 for men and r = 0.018 for women).

In the present study, the stiffness values were found to be higher in men, and therefore it is worth comparing the masseter muscle stiffness of men and women. For the masseter muscle, Arda et al. [2] reported that the stiffness was 4.6% lower in women compared to men. However, this difference was insignificant (p = 0.3). In addition, the correlation between age and masseter muscle stiffness was weak (p = 0.50).

Yoshida et al. [23] reported that the stiffness of the gastrocnemius muscle was 6% lower in women compared to men, with a *p*-value of 0.032. However, they did not examine the correlation as they did for age, which may suggest that this relationship might be not linear or could be confounded by outliers. Hence, it is difficult to draw conclusions about the sex-related differences in stiffness.

The present study has some limitations to be addressed. Firstly, SWE measurements were taken by only one experienced radiologist on a limited number of subjects. A question regarding the reliability of SWE might arise. However, SWE has already proven to be a reliable and accurate method for measuring the hardness/elasticity of soft tissues. It is also widely used in other therapeutic areas. Reports in the literature indicate that the measurements obtained using this technique are reliable and repeatable [11]. The results expressed in kPa to represent the hardness of tissues allow for comparisons between studies.

Olchowy et al. assessed the reliability of SWE measurements for the masseter muscle using intraclass correlation coefficients and observed excellent results [12]. Other researchers also proved this method to be reliable for different muscles [25–27]. Another limitation is that we examined only healthy adult subjects. The literature data show that the stiffness of the masseter muscle can increase in some disorders such as TMD [15] and after exercise [18], or decrease after applying therapeutic methods such as massage [11]. Therefore, this study shall be regarded as a reference for analyzing the disorders and conditions of the masseter muscle.

5. Conclusions

The present study showed that the stiffness of the masseter muscle was about 9% lower in women compared to men (9.48 \pm 1.47 kPa vs. 11.73 \pm 1.27 kPa; *p* < 0.0001). The masseter muscle on the left and the right side of the body had similar stiffness. Age significantly influenced the stiffness of the masseter muscle, and the value of this parameter increased significantly with age, particularly in men. However, further studies with larger samples are required to determine the precise ranges of stiffness accounting for age and sex in healthy subjects and people with disorders and conditions of the masticatory system.

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Układ stomatognatyczny jest złożony i odgrywa kluczowa rolę w wielu procesach takich jak żucie, trawienie, mowa, oddychanie, mimika i połykanie. Jego złożoność jest głównym powodem tworzenia multidyscyplinarnych zespołów zajmujących się leczeniem zaburzeń skroniowo-żuchwowych (TMD). Niniejsze badanie miało na celu ocenę sztywności mięśni żwaczy u pacjentów poddawanych leczeniu zachowawczemu zaburzeń czynnościowych mięśni żucia oraz ocenę skuteczności terapii manualnej w połączeniu z szyną zwarciową w tej grupie pacjentów. Badanie trwało 8 tygodni i miało charakter otwarty, prospektywny, bez grupy kontrolnej. Do badania właczono 35 pacjentów ze zwiększoną sztywnością mięśni narzadu żucia. Pacjenci byli leczeni terapią manualną i szyną zwarciową stabilizacyjną dla żuchwy. W czasie badania dokonano oceny sztywności mięśni żwaczy za pomocą sonoelastografii fali poprzecznej oraz oceny wyników walidowanych kwestionariuszy (Generalized Anxiety Disorder-7, Epworth Sleepiness Scale, Satisfaction with Life Scale, Perceived Stress Scale-10, Somatic Symptom Scale-8) wypełnianych przez pacjentów (patient-reported outcome measures, PROMs), analizujących ból, lęk, jakość snu, zadowolenie z życia i odczuwany stres. Wyniki badania wskazały, że po leczeniu sztywność obu mięśni żwaczy uległa znacznemu zmniejszeniu (o 4,21 kPa), a pacjenci odnotowali znaczne zmniejszenie bólu. Na początku badania mediana wyników wahała się od 5 do 8, natomiast po leczeniu wahała się od 0 do 1 (p < 0,0001). Pacjenci zgłaszali również znaczną poprawę pod względem wszystkich PROMs. Dodatkowo zmniejszenie sztywności odpowiadało zmniejszeniu bólu i poprawie innych PROMs, na co wskazują wyniki testów korelacji, jednakże ich wartości nie osiągnęły istotności statystycznej. W wyniku przeprowadzonego badania można stwierdzić, że terapia zachowawcza zaburzeń mięśnia żucia polegająca na terapii manualnej i wykorzystaniu szyny zwarciowej jest skuteczna. W wyniku leczenia zmniejszyła się sztywność mięśni żwaczy (obiektywnie potwierdzona za pomocą elastografii fali poprzecznej), jak również poprawie uległy punktacje kwestionariuszy PROMs, szczególnie w zakresie oceny bólu, ale również w zakresie pozostałych wyników

kwestionariuszy. Elastografia fali poprzecznej ma potencjał do szerokiego zastosowania w praktyce klinicznej do oceny efektów leczenia zaburzeń mięśni żucia ze względu na jej obiektywność i nieinwazyjny charakter. Zaleca się dalsze badania z grupą kontrolną na większych populacjach pacjentów i dłuższą obserwację.

RESEARCH

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Assessment of the masseter stiffness in patients during conservative therapy for masticatory muscle disorders with shear wave elastography

Anna Olchowy¹, Piotr Seweryn¹, Cyprian Olchowy² and Mieszko Wieckiewicz^{1*}

Abstract

Background: The complex structure of the stomatognathic system plays a vital role in chewing, digestion, speaking, breathing, facial expression and swallowing. Its complexity is the primary reason for creating multidisciplinary teams to manage temporomandibular disorders (TMD). We aimed to assess the masseter stiffness in patients undergoing conservative therapy for masticatory muscle disorders and evaluate the efficacy of manual therapy and stabilization occlusal splint in the treatment of masticatory muscle disorders.

Methods: This uncontrolled prospective cohort study included 35 patients with masticatory muscle disorders. The study lasted for eight weeks. The patients were treated with manual therapy and stabilization occlusal splint and evaluated using shear wave elastography of the masseter muscles and patient-reported outcome measures (PROMs) to assess pain, anxiety, quality of sleep, satisfaction with life and perceived stress.

Results: After the treatment, the stiffness of both masseter muscles decreased significantly (by 4.21 kPa). The patients reported a significant reduction in pain. At baseline, the median scores ranged from 5 to 8; after treatment, they ranged from 0 to 1 (p < 0.0001). The patients also reported significant improvement in terms of all patient-reported outcome measures. The reduction in stiffness corresponded to the improvement in pain and PROMs, as shown by correlations which were insignificant for all measures.

Conclusions: Conservative therapy of masticatory muscle disorders involving manual therapy and stabilization occlusal splint is effective. It reduces the masseter stiffness as objectively shown in shear wave elastography and improves subjective PROMs scores, including numerical pain assessment and selected questionnaires. Shear wave elastography has the potential for broad application in clinical practice to monitor masticatory muscle disorders treatment effects due to its objectivity and non-invasive character. Further research is recommended on larger patient populations and longer follow-up.

Trial registration: The study was registered at clinicaltrials.gov (NCT03844854). First posted date: 19/02/2019.

Keywords: Masseter, Shear wave elastography, Temporomandibular disorders, Occlusal splint, Massage, Masticatory muscle disorders

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Background

The stomatognathic system plays a vital role in chewing, digestion, speaking, breathing, facial expression and swallowing. In addition, its complex structure

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requires harmonious cooperation of skeletal structures (maxilla and mandible), soft tissues, temporomandibular joints and masticatory muscles [1]. This complexity is one of the reasons for creating multidisciplinary teams to manage frequently reported temporomandibular disorders (TMD).

The Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) represent a comprehensive approach to TMD diagnosis [2]. TMD patients may present with disorders in the masticatory muscles, which control the mandible movements and temporomandibular joints. Other symptoms include sounds and/or pain in temporomandibular joints (clicking and/or popping and/or crepitus), locking and limited movement of the mandible [3]. In addition, the patients may also experience symptoms that appear unrelated to the stomatognathic system, such as headache, neck and/or shoulder pain, or otolaryngological problems (e.g. tinnitus) [1, 4].

The prevalence of TMD in the Polish urban population is estimated at 55.9% [5]. The preliminary assessment can be performed by a general dentist and includes an assessment of the face and occlusal arch symmetry, palpation of masticatory muscles and temporomandibular joints, investigation of the entire dentition for number and position of teeth along with their surfaces [6]. Patients are first referred to conservative treatment, and next to surgery in the case of failure. Conservative treatment strategies aim to reduce pain and disability caused by TMD. A wide variety of techniques are used, including manual soft tissue work, splint therapy and electrophysical modalities [7]. However, TMD treatment is long and may require the participation of a more qualified dentist, physiotherapist, maxillofacial surgeon and other specialists [8]. In addition, even minor abnormalities in oral structure and function may reduce the patient quality of life [6]. Low TMD awareness [9, 10], long-term treatment and the lack of objective measures make the TMD treatment challenging.

Technological advances in diagnostic methods allowed the introduction of shear wave elastography to diagnose and monitor the treatment of masticatory muscles disorders. This method enables measuring the stiffness of soft tissues. Shear waves are generated by pressure and then detected by longitudinal ultrasonography waves that propagate in tissues significantly faster than shear waves. This method is non-invasive and shows high intra- and inter-operator agreement, high repeatability and the possibility to provide quantitative results [11, 12]. The body of evidence on the use of shear wave elastography in dentistry is growing [13]. It was validated against phantoms of known hardness [14, 15] and compared with other methods [16]. The results of shear wave elastography were proved reliable and reproducible [17, 18]. Furthermore, the literature reports suggest that this tool is reliable in measuring the changes in stiffness of the masseter muscle in response to physical therapy (namely massage) [19, 20] and exercise [21], both of which may be used in TMD management. However, there is little evidence on the use of shear wave elastography to evaluate treatment effects in patients undergoing conservative treatment for masticatory muscle disorders. With this gap in the current knowledge in mind, we performed this study among patients suffering from masticatory muscle disorders evaluating their treatment with patientreported outcome measures (PROMs) along with an objective assessment of the masseter muscles using shear wave elastography.

Objectives

The primary objective of this uncontrolled prospective cohort study was to assess the masseter stiffness in patients after a conservative therapy for masticatory muscle disorders using shear wave elastography. The secondary aim of this study was to evaluate the efficacy of manual therapy and stabilization occlusal splint in the treatment of masticatory muscle disorders. For this purpose, we investigated whether the objective measure of masseter muscle stiffness corresponded to subjective improvement in PROMs, including numerical pain assessment and selected questionnaires.

Methods

Participants

Overall, 38 people were examined of which 35 people meet inclusion criteria and were included in the study. Included patients were referred for the baseline visit directly. They gave informed written consent before the study and agreed to participate in all the study procedures. The study was approved by the Bioethics Committee at the Wroclaw Medical University (KB – 592/2018). The study was first posted on 19/02/2019 at clinicaltrials. gov (NCT03844854).

To calculate the sample size, we have taken into account our organisational and financial limitations, as well as expected estimates for the means and standard deviations that were obtained in previous studies. Additionally, we used the G* power software to calculate the total sample size of participants. The minimum sample size was 32 subjects considering the Wilcoxon test for paired samples (two groups) with a 5% level of significance, statistical power of 85%, and an average effect size of 0.5. An excess of about 10% was considered to account for possible dropouts.

Inclusion and exclusion criteria

Included patients were diagnosed with at least one of the disorders classified in group II of masticatory muscle disorders according to the DC/TMD [4, 22], namely muscle pain, contracture, hypertrophy, neoplasm, movement disorders and masticatory muscle pain attributed to systemic/central pain disorders. Exclusion criteria were the following: pharmacological treatment that can alter muscle tonus and/or reduce muscle pain (e.g. muscle relaxants, selective serotonin reuptake inhibitors, painkillers); systemic diseases, including neurological, oncological and hormonal, that can alter muscle tonus; age over 60; severe psychiatric conditions; no consent for participation in the study and other TMD treatments.

Study procedure

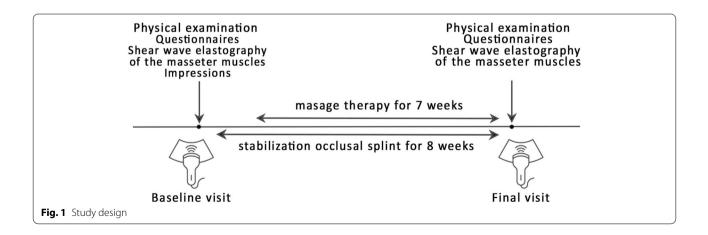
At the baseline and final visit, each patient was examined according to DC/TMD [2] using the DC/TMD international examination form, had elastography examination and filled in the questionnaires. All patients were instructed about the nature of TMD, risk factors and healthy lifestyle. In addition, impressions necessary to produce the splints were taken during the baseline visit. The patients used occlusal splints for eight weeks; manual therapy started one week later and continued for seven weeks. The rationale for choosing such study period was dictated by organizational and funding limitations, long-term institutional experience in treating patient with TMD, and results of other research that showed improvement after several weeks of treating TMD [23–25].

Figure 1 illustrates the study protocol.

Intervention

Each patient received an individually produced lower stabilization occlusal splint covering the whole mandibular teeth arch with a thickness of 3 mm. The base of the splint was made of Erkodur (Erkodent, Pfalzgrafenweiler, Germany) while the shaft was made of DURASPLINT[®] LC (Scheu, Iserlohn, Germany). The patients were advised to use the splint during sleep and partly during the day for 12 h a day in total.

Each patient underwent seven physical therapy treatments: one 45-min session per week. The therapy involved the masseter, temporal, medial pterygoid and suboccipital muscles. The suboccipital muscles were treated because of their neurophysiological connection with the trigeminocervical nucleus and consequently facial pain [26]. The therapeutic intervention consisted of extra- and intraoral techniques. All intraoral methods were applied using nitrile gloves. Therapy included kneading, transverse friction movements, stretching and releasing the trigger points. Kneading involved circular motions performed by a therapist in the area of certain muscles. It starts the therapy and increases the blood level and temperature of tissues [27]. Transverse friction movements were executed with the pressure of the fingertips on the muscle belly and by moving perpendicular to the muscle fibres. It may provoke a local inflammatory response and then reconstruction of the muscle structure [27]. Stretching was done with the patient's active opening and closing of the jaw while putting pressure on muscle fibres. This technique was applied for temporal and masseter muscles. It provides a greater range of motion and lowers muscle tension [28, 29]. Releasing the trigger points was done by finding tender points in the muscles and then applying compressive force until the pain completely disappeared. The masseter relaxation was achieved intraorally by grabbing the muscle belly with the thumb (from inside) and the index finger from the outside. The other muscles were relaxed extraorally. Therapy was conducted by a physiotherapist with six years of experience in masticatory muscle physiotherapy.



Numerical pain assessment and questionnaires

For the present study, we selected a battery of questionnaires that can be useful for the psychosocial assessment of TMD patients. We used a numerical rating scale (NRS) to evaluate pain intensity and Generalized Anxiety Disorder-7 (GAD-7) for anxiety. In addition, the patients were asked to fill in the Epworth Sleepiness Scale (ESS), Satisfaction with Life Scale (SWLS), Perceived Stress Scale (PSS) and the Somatic Symptom Scale-8 (SSS-8).

A numerical rating scale (NSR) is a standard tool for assessing pain in TMD patients [30]. We used a 10-point scale that produces results from 0 for no pain to 10 for the worst imaginable pain. In our study, it was used to evaluate six locations, namely the masseter and temporal muscles and the temporal muscle tendons on both sides.

The PSS-10 [31] is a 10-item questionnaire with a total score from 0 to 40. The version adapted and translated by Juczyński and Ogińska-Bulik [32] was employed to measure the perceived life stress among the respondents (the higher the score, the higher the level of stress). The scores ranging from 0 to 13 indicate low, from 14 to 26 moderate and from 27 to 40 high perceived stress. The GAD-7 [33] was developed to evaluate anxiety symptoms. All seven questions are scored on a 4-point Likert scale and can produce a total score ranging from 0 to 21, with higher scores denoting greater severity of measured disorders. For a score of 10 or greater, further evaluation is recommended. The scores below 5 represent minimal, 5–9 mild, 10–14 moderate and over 14 severe anxiety.

The Pittsburgh Sleep Quality Index (PSQI) [34] evaluates the quality of sleep over the past month. Nineteen questions grouped in seven components inform about sleep duration, disturbance, latency, daytime dysfunction due to sleepiness, sleep efficiency, overall sleep quality and sleep medication use. The global PSQI score can range from 0 to 21. The higher scores indicate worse sleep quality, with the cut-off>5 defining poor sleepers.

The ESS [35] was created to measure daytime sleepiness. The scale consists of 8 items that can produce scores from 0 (indicates 'would never nod off') to 3 (a strong chance of nodding off). The individual results of each item are summed, and the total score can range from 0 and 24. Higher scores indicate a higher level of daytime sleepiness. The scores from 0 to 10 denote normal sleepiness in healthy adults, 11–14 indicate mild, 15–17 moderate and 18–24 severe sleepiness.

The SWLS [36, 37] is a short instrument developed to evaluate perceived satisfaction with one's life in terms of global life satisfaction. The scale consists of 5 items that can give scores from 1 (strongly disagree) to 7 (strongly agree). The total score ranges from 5 to 35. The scores from 5 to 9 mean extreme dissatisfaction with life, 10-14 – dissatisfaction, 15-19 – slightly below average, 20-24

- average, 25–29 - satisfaction and 30–35 - high satisfaction. For both time points, only one person achieved scores below average.

The SSS-8 [38] is a brief measure of somatic symptom burden. It is an abbreviated version of the PHQ-15. The scale consists of 8 items that can give scores from 0 (not bothered at all) to 4 (very much bothered). Somatic problems are classified into no to minimal (0-3), low (4-7), medium (8-11), high (12-15) and very high (16-32).

Share wave elastography

Elastography was performed using an Aixplorer Ultimate device (SuperSonic Imagine, Aix-en-Provence, France) with a high-frequency linear probe SL 18-5 (5-18 MHz). The examinations were carried out in a supine, relaxed and comfortable position. The patients were asked not to bite down or swallow. The probe used minimal pressure on the examined tissues. The ultrasound probe was placed parallel to the long axis of the masseter in the middle of the muscle belly, where the volume of the fibres is the highest. The probe placement and patient position are based on previous research [13, 39]. The measurements were taken at the widest and thickest part of the muscle belly [40, 41]. A circular region of interest (ROI) of 4 mm was selected. Three measurements of each muscle were made and then averaged for further analysis. We reported inter- and intraobserver agreements of the measurements taken with the Aixplorer Ultimate device in the previous publication. The stiffness of the masseter muscle was rated excellent and confirmed diagnostic accuracy of shear wave elastography [18]. A radiologist with eight years of experience evaluated the masseter stiffness using shear wave elastography.

Statistical analysis

The data were statistically analysed. The Shapiro–Wilk test was used to test for normal distribution. The paired Student's t-test was employed to compare the measurements before and after the treatment for variables with normal distribution. For those with distribution other than normal, the Wilcoxon test for paired samples was applied. Differences were considered statistically significant at a *p*-value of 0 < 0.05. Statistical analysis was done with MedCalc v. 19.5.3 (MedCalc Software Ltd., Ostend, Belgium).

Results

Participants

Of the 35 generally healthy Caucasian participants, 11 were male and 24 female. Their age ranged from 19 to 58 (mean age: 29.80 ± 8.54). A diagnosis of group II of masticatory muscle disorders according to the DC/TMD [4, 22] was made in the case of all patients included. None

of the patients had previous occlusal splint therapy, nor masticatory muscle physical therapy. All participants did not have any serious abnormalities in dentition and they completed the study protocol.

Numerical pain assessment and questionnaires

The pain assessment conducted with the NRS showed that treatment eliminated pain almost entirely at each measured site. At baseline, the median scores ranged from 5 to 8; after treatment, they ranged from 0 to 1. All differences were statistically significant for p-values below 0.0001.

The patients' subjective feelings about the perceived stress and anxiety were assessed using validated questionnaires. The results of PSS-10 showed that the patients experienced moderate stress with a trend towards low stress after treatment. The PSS-10 score dropped by 0.86. This drop was significant. The results of GAD-7 showed that the mean score was below clinical significance (below 10), so they did not require further diagnosis. The scores indicated mild anxiety. At baseline, seven individuals reported a score of 10 or greater, while five individuals exceeded this cut-off value after treatment. The total mean score dropped significantly (by 0.91) in response to treatment.

Sleep was assessed with the PSQI and ESS. According to the PSQI, the study group suffered from poor sleep quality (at 2 time points, the global score was over 5), although it decreased significantly (by 0.54). According to the ESS, daytime sleepiness decreased significantly (by 0.94 points), but both measurements produced results within the normal range. A score over 10 was reported by four individuals at baseline and by two after treatment.

Life satisfaction measured by the SWLS indicated that the mean results leaned into a high score. The mean total score increased significantly (by 0.57 points). The SSS-8 showed that somatic problems dropped significantly from medium (9 points) to low (4 points). Only four patients reported no to minimal problems at baseline, but this number grew to 12 after treatment.

The results of PROMs are presented in Table 1.

Share wave elastography

The stiffness of both masseter muscles decreased significantly (by 4.21 kPa on average) (Table 2). In two patients, the stiffness did not drop or increase, and the patients did not report improvement in symptoms. Both were referred for further diagnosis; one patient was diagnosed with tetany, no follow-up information is available for the other patient.

Table 2 Share wave elastography results for the masseter

Measured site	Before	After	<i>p</i> -value
Right masseter (kPa), mean \pm SD	12.17 ± 1.16	7.90 ± 1.73	< 0.0001*
Left masseter (kPa), mean \pm SD	12.18 ± 1.18	8.01 ± 1.69	< 0.0001*
Total measurements (kPa), mean \pm SD	12.17±1.17	7.96±1.70	< 0.0001*

SD Standard deviation

* Wilcoxon test for paired samples

Table 1 Results of numerical pain assessment and questionnaire scores

Muscle / Scale	Before	After	<i>p</i> -value
NRS, right masseter, median (IQR)	7 (5.25–7.00)	1 (1.00–1.75)	< 0.0001*
NRS, left masseter, median (IQR)	6 (5.00-7.00)	1 (1.00–2.00)	< 0.0001*
NRS, right temporal muscle, median (IQR)	5 (3.00-6.00)	1 (0.00-1.00)	< 0.0001*
NRS, left temporal muscle, median (IQR)	5 (3.00–6.00)	0 (0.00-1.00)	< 0.0001*
NSR, right temporal muscle tendon, median (IQR)	8 (7.00-8.00)	1 (1.002–.00)	< 0.0001*
NSR, left temporal muscle tendon, median (IQR)	8 (7.00-8.00)	1 (1.00-2.00)	< 0.0001*
PSS-10, mean \pm SD	14.66 ± 6.06	13.80 ± 5.94	0.0917**
GAD-7, mean \pm SD	6.71 ± 3.43	5.80 ± 3.26	0.0003**
PSQI, mean \pm SD	7.83 ± 2.43	7.29 ± 2.22	0.0097**
ESS, mean \pm SD	6.17 ± 3.08	5.23 ± 2.96	< 0.0001**
SWLS, mean ± SD	26.69 ± 3.84	27.26 ± 3.85	0.0008**
SSS-8, median (IQR)	9 (6.25–12.00)	4 (3.00-5.75)	< 0.0001*

ESS Epworth Sleepiness Scale, GAD-7 Generalized Anxiety Disorder-7, IQR Interquartile range, NRS numerical rating scale, PSQI Pittsburgh Sleep Quality Index, PSS Perceived Stress Scale, SD Standard deviation, SSS-8 Somatic Symptom Scale-8 (SSS-8), SWLS Satisfaction with Life Scale

* Wilcoxon test for paired samples

** paired samples t-test

Table 3 Relationshi	ps between the changes in stiffness	s, numerical pain assessment and c	juestionnaires scores

Muscle / Scale	Difference, mean \pm SD	Correlation with stiffness, correlation coef.; <i>p</i> -value		
		right masseter	left masseter	
Stiffness in the right masseter	4.17±1.47			
Stiffness in the left masseter	4.26 ± 1.48			
NRS for the right masseter	5.14 ± 1.52	0.1461; 0.4024		
NRS for the left masseter	5.00 ± 1.5		0.4396; 0.0082	
PSS-10	0.86 ± 2.92	-0.0917; 0.6002	-0.0511; 0.7708	
GAD-7	0.91 ± 1.36	-0.1746; 0.3158	-0.1412; 0.4185	
PSQI	0.54 ± 1.17	0.1195; 0.4942	0.0212; 0.9038	
ESS	0.94±1.11	0.1063; 0.5434	0.1003; 0.5663	
SWLS	-0.57 ± 0.92	-0.0660; 0.7063	-0.1628; 0.3501	
SSS-8	5.29±4.29	-0.0201; 0.9086	-0.0088; 0.9602	

ESS Epworth Sleepiness Scale, GAD-7 Generalized Anxiety Disorder-7, IQR Interquartile range, NRS numerical rating scale, PSQ/ Pittsburgh Sleep Quality Index, PSS Perceived Stress Scale, SD Standard deviation, SSS-8 Somatic Symptom Scale-8 (SSS-8), SWLS Satisfaction with Life Scale

Correlations between the change in PROMs and masseter stiffness

First, we calculated mean changes in somatic and mental measures and the masseter stiffness achieved in response to applied treatment. The total mean reduction in stiffness after the treatment in comparison with the baseline was 4.22 ± 1.47 kPa. The relationships between scales and the reduction in stiffness were not significant (Table 3). The correlation between baseline subjective measure scores and stiffness for both sides was significant or tended to be significant only for GAD (left: r=-0.3725; p=0.0275; right: r=-0.333; p=0.0506).

Discussion

Our study showed a significant improvement after masticatory muscle disorders treatment. Improvement in numerical pain assessment and questionnaire scores and decreased masseter stiffness were observed. An improvement in subjective PROMs, including perceived pain, anxiety, stress, quality of sleep, satisfaction with life and perceived somatic symptoms, corresponds to the reduction of stiffness of the masseter muscle as objectively measured with shear wave elastography.

TMD therapy is challenging. TMD is an umbrella term that includes various conditions affecting the morphology and function of the masticatory system. On top of this, numerous factors complicate the diagnosis and treatment of TMD, including those related to dentition, teeth grinding/clenching, systemic diseases and local neuromuscular pathologies [42]. TMD treatment aims to eliminate pain, joint sounds and improve mouth opening and jaw movements. Conservative therapies include interventions directed to change lifestyle (mainly to reduce stress), physiotherapy and occlusal splints [43]. In this study, we used conservative treatment, as it is proved to be effective, less aggressive and satisfactory for patients [42]. Treatment monitoring is based mostly on the physical examination and PROMs, which are subjective in nature. Currently, shear wave elastography is not applied to assess the masseter muscle stiffness in TMD patients. However, several reports proved its usefulness in evaluating the masseter muscle condition both in healthy volunteers and patients with diagnosed TMD [18, 19, 21, 44]. Still, there was a gap in evidence on monitoring TMD patients with shear wave elastography. Previous reports showed effectiveness to detect improvement after short term exposure to massage or exercise [19, 21]. After such treatment, the stiffness of the masseter muscle dropped from 12.17 ± 1.17 kPa to 7.96 ± 1.70 kPa (p < 0.0001). The present study showed a significant decrease in masseter muscle stiffness by 4.22 ± 1.47 kPa on average. This study justifies the use of shear wave elastography to assess long-term treatment.

As shear wave elastography can detect changes in the stiffness of the masseter with high precision, we aimed to investigate whether the benefits of manual therapy and stabilization occlusal splint in the treatment of masticatory muscle disorders can be shown using shear wave elastography. Correlations between the change in stiffness and PROM scores were not significant, which indicates that clinical drop in muscle stiffness corresponded to the improvement reported by patients in subjective measures. We did not find similar studies involving shear wave elastography in the literature, yet previous research showed that both massage and occlusal splints can effectively reduce masseter muscle stiffness. Researchers conclude that the drop in stiffness after massage [19, 20] can be due to relaxation of the tissues caused by increased blood flow and temperature of the treated tissue [45];

however, the biomechanism of massage has not been explained. Occlusal splints are widely used for treating TMD in patients with muscle-related disorders, although the evidence might be considered inconclusive. Occlusal splints reduce fatigue in the masseter muscles, ensure stable dental occlusion, reduce occlusal interferences, and minimise neuromuscular activity [46].

Benefits provided by shear wave elastography for TMD patients go beyond measuring stiffness and monitoring the treatment results. In the present study, we were able to identify two patients who did not respond to treatment (one completely, one partially). Although the patients reported a minimal clinical improvement, the masseter muscle stiffness increased in both. This finding prompted us to refer non-responsive patients for further diagnosis. Both patients were diagnosed with tetany. Tetany involves muscle contractions, but its aetiology is different and associated with hypocalcaemia [47]. Also, tetany has a variable clinical presentation, which poses a challenge for differential diagnosis [48]. We did not track down any report describing tetany in patients undergoing TMD treatment; however, this could be due to the lack of sensitive methods to distinguish those disorders. Using shear wave elastography, we could objectively measure that those patients had no improvement in terms of masseter muscle stiffness which allowed us to conclude that they were misdiagnosed. The patients were unaware of the condition at the time of enrolment in the study.

Limitations

Several limitations have to be kept in mind when interpreting the study findings. First, this study included a relatively small number of subjects. The study offered an intensive treatment; therefore, only highly motivated and committed patients could participate. Second, the study lacks a control group. It would add more value to our results; however, we considered it ethically controversial to leave patients suffering from TMD without treatment and merely observe them. And finally, our study lasted eight weeks including seven weeks of massage therapy and eight week od occlusal splints wearing only without a long-term follow-up due to financial, organizational and time constraints. Nevertheless, it was sufficient for a short-term assessment that showed the benefits of manual therapy and the application of stabilization occlusal splint for masticatory muscle disorders treatment. However, further questions about maintenance therapy and the possibility of relapse after treatment remain open.

Conclusions

Conservative therapy of masticatory muscle disorders involving manual therapy and stabilization occlusal splint is effective. It reduces the masseter stiffness as objectively shown in shear wave elastography and improves subjective PROMs scores, including numerical pain assessment and selected questionnaires. Shear wave elastography has the potential for broad application in clinical practice to monitor a masticatory muscle disorders treatment effects due to its objectivity and non-invasive character. Further research is recommended on larger patient populations and longer follow-up.

Abbreviations

ESS: Epworth Sleepiness Scale; GAD-7: Generalized Anxiety Disorder-7; IQR: Interquartile range; NRS: Numerical rating scale; PSQI: Pittsburgh Sleep Quality Index; PROM: Patient-reported outcome measure; PSS: Perceived Stress Scale; SD: Standard deviation; SSS-8: Somatic Symptom Scale-8 (SSS-8); SWLS: Satisfaction with Life Scale; TMD: Temporomandibular disorders.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12891-022-05392-9.

Additional file 1.

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Authors' contributions

AO designed the study and methodology, carried out the experiments, conducted the statistical analysis, interpreted the experimental data and was a major contributor to the writing of the manuscript. PS carried out the experiments and contributed to the interpretation of data and manuscript writing. CO designed the study and methodology, carried out the experiments and critically revised the manuscript for important intellectual content. MW designed the study and methodology, interpreted the experimental data and critically revised the manuscript for important intellectual content. All authors have read and approved the final manuscript and agreed to its publication.

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Availability of data and materials

All data generated or analysed during this study are included in this published article and its supplementary information file.

Declarations

Ethics approval and consent to participate

All participants took part in the study voluntarily and gave informed consent. The study was conducted according to the Declaration of Helsinki and was approved by the Bioethics Committee at Wroclaw Medical University (KB – 592/2018).

Consent for publication

Not applicable.

Competing interests

The authors declare no conflict of interest.

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VII. PODSUMOWANIE WYNIKÓW

Zaburzenia skroniowo-żuchwowe (temporomandibular disorders, TMD) stanowią poważny i częsty problem diagnostyczno-leczniczy w praktyce stomatologicznej. W polskiej populacji ogólnej, TMD mogą dotyczyć nawet do 55,9% populacji osób dorosłych. Do charakterystycznych objawów zalicza należą ból mięśni narządu żucia i/lub stawów skroniowo-żuchwowych, objawy dźwiękowe w stawach skroniowo-żuchwowych (trzaski, trzeszczenie) oraz nieprawidłowe ruchy żuchwy. Dodatkowo występują objawy z otaczających tkanek i narządów.

Diagnostyka TMD opiera się na kryteriach Diagnostic Criteria for Temporomandibular Disorders (DC-TMD), ale stanowi wyzwanie m.in. z powodu ograniczeń dotyczących obiektywności. Pomiar sztywności mięśni żwaczy wykonany w oparciu o metodę sonoelastografii fali poprzecznej (shear wave elastography, SWE) może wypełnić tą lukę, gdyż pozwala w sposób obiektywny, nieinwazyjny i bezpieczny na wykonanie pomiaru sztywności mięśni żwaczy. Jednakże każdy organ posiada własną charakterystykę i odchylenia od normy w stanach patologicznych.

Dzięki badaniu poświęconemu ustaleniu wartości referencyjnych sztywności mięśnia żwacza u zdrowych osób dorosłych za pomocą sonoelastografii fali poprzecznej ustalono zakres wartości średnich u zdrowych ochotników. Wiek i płeć były istotnymi czynnikami wpływających na sztywność mięśnia żwacza. Zgodnie z otrzymanymi wynikami, ogólna średnia sztywność wyniosła 10,67 \pm 1,77 kPa. Średnie wartości były niższe o 2,25 kPa (9,15%) u kobiet w porównaniu z mężczyznami (9,48 \pm 1,47 kPa vs 11,73 \pm 1,27 kPa; p < 0,0001). Wartości sztywności wzrastały wraz z wiekiem, przy współczynniku korelacji około 0,35 i p < 0,0001.

Ustalenie wartości referencyjnych badania sztywności mięśni żwaczy metodą sonoelastografii fali poprzecznej stanowi punkt wyjściowy do dalszych badań. Dzięki temu można obiektywnie porównywać grupy pacjentów oraz oceniać efekty leczenia w czasie. W 8 tygodniowym badaniu przeprowadzonym wśród pacjentów poddawanych leczeniu zachowawczemu zaburzeń mięśni żucia (terapia manualna wraz z szyną zwarciową) oceniono skuteczność leczenia w osób obiektywny (sonoelastografia) i subiektywny (wyniki walidowanych kwestionariuszy wypełnianych przez pacjentów). Wyniki badania wskazały, że po leczeniu sztywność obu mięśni żwaczy uległa znacznemu zmniejszeniu (o 4,21 kPa), a pacjenci odnotowali znaczne zmniejszenie bólu. Subiektywna poprawa przełożyła się na

zmniejszenie sztywności mięśni żwaczy, a zatem sonoelastografia wykazała swoją użyteczność w ocenie postępów leczenia u pacjentów z TMD.

W wyniku przeprowadzonych badań można stwierdzić, że sonoelastografia fali poprzecznej jest obiektywnym narzędziem do oceny sztywności mięśni żwaczy oraz oceny prowadzonego leczenia u pacjentów z TMD. Sonoelastografia jest bezpieczna, nieinwazyjna i pozbawiona negatywnych doznań dla pacjentów.

VIII. WNIOSKI

Na podstawie przeprowadzonych badań wyciągnięto następujące wnioski:

- Systematyczny przegląd literatury usystematyzował obecną wiedzę na temat stosowania elastografii w ocenie mięśnia żwaczy u osób zdrowych i pacjentów z zaburzeniami mięśni żwaczy, a tym samym wskazał na konieczność przeprowadzenia badań do większych grupach pacjentów w celu określenia dokładności elastografii fali poprzecznej w ocenie zaburzeń mięśni żucia.
- 2. Sonoelastografia fali poprzecznej jest wiarygodnym narzędziem do oceny sztywności mięśni żwaczy. Dzięki włączeniu sonoelastografii w proces diagnostyczny możliwe jest skrócenie i poprawienie jakości procesu diagnostycznego. Włączenie sonoelastografii w proces oceny leczenia umożliwia jest obiektywne porównanie wyników w czasie leczenia pacjenta. Sonoelastografia jest bezpieczna, nieinwazyjna i pozbawiona negatywnych doznań dla pacjentów.
- 3. Mięsień żwacz, podobnie jak inne mięśnie poprzecznie prążkowane, ma swój unikalny zakres normy wartości sztywności. U zdrowych ochotników wartość sztywności mięśni żwaczy było obustronnie symetryczna. Do czynników istotnie wpływających na sztywność mięśnia żwacza należą płeć i wiek. Sztywność mięśni żwaczy jest niższa u kobiet niż u mężczyzn. Wartość sztywności istotnie wzrastała z wiekiem, szczególnie u mężczyzn. Wyniki badania sztywności metodą sonoelastografii fali poprzecznej są powtarzalne.
- 4. Zachowawcza terapia prowadzona u pacjentów z TMD obejmująca terapię manualną wraz z zastosowaniem szyny zwarciowej daje pozytywne efekty w zakresie badanych obiektywnych i subiektywnych parametrów. Po leczeniu stwierdzono u pacjentów spadek sztywności mięśni żwaczy za pomocą obiektywnej metody jaką jest

sonoelastografia fali poprzecznej. Obiektywna poprawa nastąpiła równolegle do poprawy subiektywnej w zakresie badanych PROMs. Sonoelastografia fali poprzecznej ma potencjał do szerokiego zastosowania w praktyce klinicznej do oceny leczenia TMD ze względu na jej obiektywizm, nieinwazyjny charakter i bezpieczeństwo. Niemniej jednak należy kontynuować badania z grupą kontrolną na większej populacji pacjentów i z dłuższym czasem obserwacji.

IX. PIŚMIENNICTWO

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X. ZAŁĄCZNIKI

1. INFORMACJA O ŹRÓDŁACH FINANSOWANIA BADAŃ

Badania zostały przeprowadzone w ramach grantu 'Shear Wave Sonoelastography in the Diagnosis and Management of the Masseter Muscles Disorders' finansowanego przez Narodowe Centrum Nauki (numer grantu: 2017/27/N/NZ5/02690).

2. OŚWIADCZENIA WSPÓŁAUTORÓW PRAC

Lek. dent. Anna Olchowy Katedra i Zakład Stomatologii Doświadczalnej Uniwersytet Medyczny im. Piastów Śląskich we Wrocławiu

OŚWIADCZENIA

1. Oświadczam, że w publikacji: Great potential of ultrasound elastography for the assessment of the masseter muscle in patients with temporomandibular disorders. A systematic review. ANNA OLCHOWY, MIESZKO WIĘCKIEWICZ, EFRAIM WINOCUR, MARZENA DOMINIAK, ILONA DEKKERS, MATEUSZ ŁASECKI, CYPRIAN OLCHOWY. Dentomaxillofac.Radiol. 2020 Vol.49 no.8 art.20200024 [9 s.], ryc., tab., bibliogr. 36 poz., summ. DOI: 10.1259/dmfr.20200024, mój wkład polegał na stworzeniu koncepcji pracy; pozyskiwaniu, analizie i interpretacji danych, pisaniu oraz korekcie manuskryptu.

2. Oświadczam, że w publikacji: Determination of reference values of the masseter muscle stiffness in healthy adults using shear wave elastography. ANNA OLCHOWY, MIESZKO WIĘCKIEWICZ, ANDRZEJ MAŁYSA, CYPRIAN OLCHOWY. Int.J.Environ.Res.Public Health 2021 Vol.18 no.17 art.9371 [8 s.], ryc., tab., bibliogr. 27 poz., summ. DOI: 10.3390/ijerph18179371, mój wkład polegał na stworzeniu koncepcji, analizie zebranych danych, pozyskaniu finansowania na badanie, nadzorowaniu i przeprowadzeniu badania, określeniu metodologii, napisaniu oraz ostatecznej korekcie publikacji.

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3. Oświadczam, że w publikacji: Assessment of the masseter stiffness in patients during conservative therapy for masticatory muscle disorders with shear wave elastography. ANNA OLCHOWY, PIOTR SEWERYN, CYPRIAN OLCHOWY, MIESZKO WIĘCKIEWICZ. BMC Musculoskelet.Disord. 2022 Vol.23 art.439 [9 s.], ryc., tab., bibliogr. 48 poz., summ. DOI: 10.1186/s12891-022-05392-9, polegał na zaprojektowaniu badania i jej metodyki, przeprowadzeniu badania, analizie danych, napisaniu i korekcie manuskryptu.

fine dany

Dr hab. n. med. Cyprian Olchowy Uniwersytet Medyczny im. Piastów Śląskich We Wrocławiu

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1. Oświadczam, że w publikacji: Great potential of ultrasound elastography for the assessment of the masseter muscle in patients with temporomandibular disorders. A systematic review. ANNA OLCHOWY, MIESZKO WIĘCKIEWICZ, EFRAIM WINOCUR, MARZENA DOMINIAK, ILONA DEKKERS, MATEUSZ ŁASECKI, CYPRIAN OLCHOWY. Dentomaxillofac.Radiol. 2020 Vol.49 no.8 art.20200024 [9 s.], ryc., tab., bibliogr. 36 poz., summ. DOI: 10.1259/dmfr.20200024, mój wkład polegał na stworzeniu koncepcji, analizie i interpretacji danych, korekcie publikacji, ostatecznej akceptacji pracy.

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Prof. dr hab. n. med. Marzena Dominiak Katedra i Zakład Chirurgii Stomatologicznej Uniwersytet Medyczny im. Piastów Śląskich We Wrocławiu

OŚWIADCZENIE

1. Oświadczam, że w publikacji: Great potential of ultrasound elastography for the assessment of the masseter muscle in patients with temporomandibular disorders. A systematic review. ANNA OLCHOWY, MIESZKO WIĘCKIEWICZ, EFRAIM WINOCUR, MARZENA DOMINIAK, ILONA DEKKERS, MATEUSZ ŁASECKI, CYPRIAN OLCHOWY. Dentomaxillofac.Radiol. 2020 Vol.49 no.8 art.20200024 [9 s.], ryc., tab., bibliogr. 36 poz., summ. DOI: 10.1259/dmfr.20200024, mój wkład polegał na interpretacji danych, korekcie oraz ostatecznej akceptacji publikacji.

czny we Wrocławiu RA I ZAKŁAD CHIRURGI ana Dominiak

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Dr n. med. Mateusz Łasecki Katedra Radiologii Uniwersytet Medyczny im. Piastów Śląskich We Wrocławiu

OŚWIADCZENIE

1. Oświadczam, że w publikacji: Great potential of ultrasound elastography for the assessment of the masseter muscle in patients with temporomandibular disorders. A systematic review. ANNA OLCHOWY, MIESZKO WIĘCKIEWICZ, EFRAIM WINOCUR, MARZENA DOMINIAK, ILONA DEKKERS, MATEUSZ ŁASECKI, CYPRIAN OLCHOWY. Dentomaxillofac.Radiol. 2020 Vol.49 no.8 art.20200024 [9 s.], ryc., tab., bibliogr. 36 poz., summ. DOI: 10.1259/dmfr.20200024, mój wkład polegał na pozyskiwaniu danych i ich interpretacji, pisaniu i korekcie publikacji.

Mateusz Lasecki

Mgr. Piotr Seweryn

Katedra i Zakład Stomatologii Doświadczalnej Uniwersytet Medyczny im. Piastów Śląskich we Wrocławiu

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Prof. dr hab. n. med. Mieszko Więckiewicz Katedra i Zakład Stomatologii Doświadczalnej Uniwersytet Medyczny im. Piastów Śląskich We Wrocławiu

OŚWIADCZENIA

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Mules Weller

2. Oświadczam, że w publikacji: **Determination of reference values of the masseter muscle stiffness in healthy adults using shear wave elastography**. ANNA OLCHOWY, MIESZKO WIĘCKIEWICZ, ANDRZEJ MAŁYSA, CYPRIAN OLCHOWY. Int.J.Environ.Res.Public Health 2021 Vol.18 no.17 art.9371 [8 s.], ryc., tab., bibliogr. 27 poz., summ. DOI: 10.3390/ijerph18179371, mój wkład polegał na stworzeniu koncepcji, analizie zebranych danych, pozyskaniu finansowania na badania, ostatecznej korekcie i akceptacji publikacji.

Mielio Wychen

3. Oświadczam, że w publikacji: Assessment of the masseter stiffness in patients during conservative therapy for masticatory muscle disorders with shear wave elastography. ANNA OLCHOWY, PIOTR SEWERYN, CYPRIAN OLCHOWY, MIESZKO WIĘCKIEWICZ. BMC Musculoskelet.Disord. 2022 Vol.23 art.439 [9 s.], ryc., tab., bibliogr. 48 poz., summ. DOI: 10.1186/s12891-022-05392-9, polegał na zaprojektowaniu badania wraz z metodyką, analizie danych, ostatecznej korekcie publikacji.

Mulio Wieden

Prof. Dr. Efraim Winocur Department of Oral Rehabilitation, Tel Aviv University, Tel Aviv, Israel

OŚWIADCZENIE/DECLARATION

1. Oświadczam, że w publikacji: **Great potential of ultrasound elastography for the assessment of the masseter muscle in patients with temporomandibular disorders. A systematic review**. ANNA OLCHOWY, MIESZKO WIĘCKIEWICZ, EFRAIM WINOCUR, MARZENA DOMINIAK, ILONA DEKKERS, MATEUSZ ŁASECKI, CYPRIAN OLCHOWY. Dentomaxillofac. Radiol. 2020 Vol.49 no.8 art.20200024 [9 s.], ryc., tab., bibliogr. 36 poz., summ. DOI: 10.1259/dmfr.20200024, mój wkład polegał na interpretacji danych, korekcie publikacji, akceptacji ostatecznej wersji pracy.

1. I declare that in manuscript : Great potential of ultrasound elastography for the assessment of the masseter muscle in patients with temporomandibular disorders. A systematic review. ANNA OLCHOWY, MIESZKO WIĘCKIEWICZ, EFRAIM WINOCUR, MARZENA DOMINIAK, ILONA DEKKERS, MATEUSZ ŁASECKI, CYPRIAN OLCHOWY. Dentomaxillofac. Radiol. 2020 Vol.49 no.8 art.20200024 [9 s.], ryc., tab., bibliogr. 36 poz., summ. DOI: 10.1259/dmfr.20200024 my contribution was to interpretation of data for the work, revising the manuscript for important intellectual content, final approval of the version to be published.

Ewinoan

Prof. Efraim Winocur

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Podpis/signature

Wrocław, 12.07.2022

Ilona Dekers, MD, PhD Department of Radiology, Leiden University Medical Center, Leiden, the Netherlands

OŚWIADCZENIE/DECLARATION

Oświadczam, że w publikacji: Great potential of ultrasound elastography for the assessment of the masseter muscle in patients with temporomandibular disorders. A systematic review. ANNA OLCHOWY, MIESZKO WIĘCKIEWICZ, EFRAIM WINOCUR, MARZENA DOMINIAK, ILONA DEKKERS, MATEUSZ ŁASECKI, CYPRIAN OLCHOWY. Dentomaxillofac.Radiol. 2020 Vol.49 no.8 art.20200024 [9 s.], ryc., tab., bibliogr. 36 poz., summ. DOI: 10.1259/dmfr.20200024, mój wkład polegał na interpretacji danych, pisaniu publikacji, akceptacji ostatecznej wersji pracy.

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Lek. dent. Andrzej Małysa

Katedra i Zakład Stomatologii Doświadczalnej Uniwersytet Medyczny im. Piastów Śląskich we Wrocławiu

OŚWIADCZENIE

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Audrep holyne

3. ZGODA KOMISJI BIOETYCZNEJ

KOMISJA BIOETYCZNA przy Uniwersytecie Medycznym we Wrocławiu ul. Pasteura 1; 50-367 WROCŁAW

OPINIA KOMISJI BIOETYCZNEJ Nr KB - 592/2018

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) (pediatria, choroby zakaźne) dr hab. Leszek Szenborn Danuta Tarkowska (pielęgniarstwo) prof. dr hab. Anna Wiela-Hojeńska (farmakologia kliniczna) dr hab. Andrzej Wojnar (histopatologia, dermatologia) przedstawiciel Dolnośląskiej Izby Lekarskiei) 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.

"Ocena przydatności sonoelastografii fali poprzecznej w diagnostyce i monitorowaniu postępów leczenia zwiększonego napięcia mięśni żwaczy w przebiegu dysfunkcji narządu żucia" zgłoszonym przez lek. dent. Annę Olchowy uczestniczkę studiów doktoranckich w Katedrze i Zakładzie Stomatologii Doświadczalnej Uniwersytetu Medycznego we Wrocławiu oraz złożonymi wraz z wnioskiem dokumentami, w tajnym głosowaniu postanowiła wyrazić zgodę na przeprowadzenie badania w Poradni Dysfunkcji Narządu Żucia Katedry i Zakładu Stomatologii Doświadczalnej Akademickiej Polikliniki Stomatologicznej we Wrocławiu pod warunkiem zachowania anonimowości uzyskanych danych.

<u>Uwaga:</u> 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 finansowanego z Narodowego Centrum Nauki – Numer rejestrowy Centrum Wspierania Nauki UMW: PREL.B160.18.007

Wrocław, dnia 24 października 2018 r. Uniwersytet Medvczn **KOMISJAB** YCZNA przev BW prof. dr hab.

4. NOTA BIOGRAFICZNA

Anna Olchowy urodziła się 12 marca 1992 r. w Wieluniu. W 2011 ukończyła I Liceum Ogólnokształcące im. Marii Skłodowskiej Curie w Ostrzeszowie. W 2012 r. rozpoczęła studia na Kierunku Lekarsko-Dentystycznym Wydziału Lekarsko- Stomatologicznego Uniwersytetu Medycznego im. Piastów Śląskich we Wrocławiu. Podczas studiów była aktywnym członkiem Studenckiego Koła Naukowego Ortopedii Szczękowej i Ortodoncji. W roku 2017 r. ukończyła studia uzyskując tytuł lekarza dentysty. W 2017 r. rozpoczęła studia doktoranckie w Katedrze i Zakładzie Stomatologii Doświadczalnej na Wydziale Lekarskim Kształcenia Podyplomowego Uniwersytetu Medycznego im. Piastów Śląskich we Wrocławiu. Przez cały okres studiów doktoranckich otrzymywała stypendium dla najlepszych studentów. W 2018 r. otrzymała Grant Narodowego Centrum Nauki Preludium 14. W 2019 r. otrzymała stypendium programu POWER Dolnośląscy Liderzy Medycyny.

Liczba opublikowanych prac: 16 (suma pkt. MEiN: **1420**, IF: **43,244**) Doniesienia zjazdowe: 2 krajowe; 6 o zasięgu międzynarodowym.

Dane z bazy Web of Science z dnia 14 września 2022. INDEKS HIRSCHA: **5** LICZBA CYTOWAŃ BEZ AUTOCYTOWAŃ: **169**

5. WYKAZ PUBLIKACJI AUTORKI

Sumaryczny Impact Factor: 43,244.

Lp.	Opis bibliograficzny	Rok	IF	РК	Typ KBN
1.	Olchowy C, Cebulski K, Łasecki M, Chaber R, Olchowy A, Kałwak K, Zaleska-Dorobisz U. The presence of the gadolinium-based contrast agent depositions in the brain and symptoms of gadolinium neurotoxicity - A systematic review. PLoS One. 2017;12(2):e0171704. doi: 10.1371/journal.pone.0171704	2017	2,766	40,00	Praca oryginalna

2.	Olchowy C, Maciąg EJ, Sanchez-Montanez A, Olchowy A, Delgado I, Vazquez E. Measurements of signal intensity of globus pallidus and dentate nucleus suggest different deposition characteristics of macrocyclic GBCAs in children. PLoS One. 2018;13(12):e0208589. doi: 10.1371/journal.pone.0208589	2018	2,766	40,00	Praca oryginalna
3.	Florjanski W, Malysa A, Orzeszek S, Smardz J, Olchowy A, Paradowska-Stolarz A, Wieckiewicz M. Evaluation of Biofeedback Usefulness in Masticatory Muscle Activity Management-A Systematic Review. J Clin Med. 2019;8(6):766. doi: 10.3390/jcm8060766	2019	3,303	140,00	Praca przeglądowa
4.	Florjanski W, Orzeszek S, Olchowy A , Grychowska N, Wieckiewicz W, Malysa A, Smardz J, Wieckiewicz M. Modifications of Polymeric Membranes Used in Guided Tissue and Bone Regeneration. Polymers (Basel). 2019;11(5):782. doi:10.3390/polym11050782	2019	3,426	100,00	Praca przeglądowa
5.	Olchowy A, Olchowy C, Łasecki M, Mazur R, Sierpowska M, Waligóra M, Więckiewicz M. Ovarian Hyperstimulation Syndrome as a Growing Diagnostic Problem in Emergency Department Settings: A Case Report. J Emerg Med. 2019;56(2):217-221. doi: 10.1016/j.jemermed.2018.11.004	2019	1,224	70,00	Praca kazuistyczna
6.	Olchowy A , Wieckiewicz M, Winocur E, Dominiak M, Dekkers I, Łasecki M, Olchowy C. Great potential of ultrasound elastography for the assessment of the masseter muscle in patients with temporomandibular disorders. A systematic review. Dentomaxillofac Radiol. 2020;49(8):20200024. doi: 10.1259/dmfr.20200024	2020	2,419	100,00	Praca przeglądowa
7.	Chaber R, Łasecki M, Kuczyński K, Cebryk R, Kwaśnicka J, Olchowy C, Łach K, Pogodajny Z, Koptiuk O, Olchowy A , Popecki P, Zaleska- Dorobisz U. Hounsfield units and fractal dimension (test HUFRA) for determining PET positive/negative lymph nodes in pediatric Hodgkin's lymphoma patients. PLoS One. 2020;15(3):e0229859. doi: 10.1371/journal.pone.0229859	2020	3,240	100,00	Praca oryginalna

8.	Olchowy C, Więckiewicz M, Sconfienza LM, Łasecki M, Seweryn P, Smardz J, Hnitecka S, Dominiak M, Olchowy A . Potential of Using Shear Wave Elastography in the Clinical Evaluation and Monitoring of Changes in Masseter Muscle Stiffness. Pain Res Manag. 2020;2020:4184268. doi: 10.1155/2020/4184268	2020	3,037	70,00	Praca oryginalna
9.	Dominiak M, Hnitecka S, Olchowy C, Olchowy A , Gedrange T. Analysis of alveolar ridge width in an area of central lower incisor using cone-beam computed tomography in vivo. Ann Anat. 2021;236:151699. doi: 10.1016/j.aanat.2021.151699	2021	2,698	100,00	Praca oryginalna
10.	Olchowy C, Olchowy A , Hadzik J, Dąbrowski P, Mierzwa D. Dentists can provide reliable shear wave elastography measurements of the stiffness of masseter muscles: A possible scenario for a faster diagnostic process. Adv Clin Exp Med. 2021;30(6):575-580. doi: 10.17219/acem/134875	2021	1,727	70	Praca oryginalna
11.	Olchowy A , Więckiewicz M, Malysa A, Olchowy C. Determination of Reference Values of the Masseter Muscle Stiffness in Healthy Adults Using Shear Wave Elastography. Int J Environ Res Public Health. 2021;18(17):9371. doi: 10.3390/ijerph18179371	2021	3,390	140,00	Praca oryginalna
12.	Olchowy C, Grzech-Leśniak K, Hadzik J, Olchowy A , Łasecki M. Monitoring of Changes in Masticatory Muscle Stiffness after Gum Chewing Using Shear Wave Elastography. J Clin Med. 2021;10(11):2480. doi: 10.3390/jcm10112480	2021	4,242	140,00	Praca oryginalna
13.	Olchowy C, Olchowy A , Pawluś A, Więckiewicz M, Sconfienza LM. Stiffness of the Masseter Muscle in Children-Establishing the Reference Values in the Pediatric Population Using Shear- Wave Elastography. Int J Environ Res Public Health. 2021;18(18):9619. doi: 10.3390/ijerph18189619.	2021	3,390	140,00	Praca oryginalna
14.	Olchowy A , Seweryn P, Olchowy C, Wieckiewicz M. Assessment of the masseter stiffness in patients during conservative therapy for masticatory muscle disorders with shear wave elastography. BMC Musculoskelet Disord. 2022;23(1):439.	2022	2,355	100,00	Praca oryginalna

Mierzwa D, Olchowy C, Olchowy A , Nawrot- Hadzik I, Dąbrowski P, Chobotow S, Grzech- Leśniak K, Kubasiewicz-Ross P, Dominiak M. Botox Therapy for Hypertrophy of the Masseter Muscle Causes a Compensatory Increase of Stiffness of Other Muscles of Masticatory Apparatus. Life (Basel). 2022 Jun 6;12(6):840. doi: 10.3390/life12060840.	2022	3,251	70,00	Praca oryginalna
SUMA		43,244	1420	