PROTOCOL
The Emotional and Functional Benefits of Poly-L-Lactic Acid
YDA-001

Study Sponsor:
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Yardley Clinical Research Associates
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Yardley, PA 19067

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CONFIDENTIAL

PROTOCOL APPROVAL PAGE

INVESTIGATOR SIGNATURE PAGE

I agree to:

- Implement and conduct this study diligently and in strict compliance with the protocol, good clinical practices and all applicable laws and regulations.
- Maintain all information supplied by Yardley Dermatology Associates, PC, Yardley Clinical Research Associates or its designate in confidence and, when this information is submitted to an Institutional Review Board (IRB)or another group, it will be submitted with a designation that the material is confidential.

I have read this protocol in its entirety and I agree to all aspects.

Investigator Printed Name	Signature	Date

STUDY PERSONNEL CONTACT INFORMATION

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GLOSSARY OF ABBREVIATIONS

CFR	U. S. Code of Federal Regulations
CRF	Case Report Form
DHHS	Department of Health and Human Services
GCP	Good Clinical Practices
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IRB	Independent Review Board
PP	Per protocol
WHOdd	World Health Organization Drug Dictionary

PROTOCOL SYNOPSIS

Title	The Emotional and functional benefits of Poly-L-Lactic Acid
Study Objective	To assess the emotional and functional benefits of Poly-L-Lactic Acid injections in the face
Study Population	Male and female subjects ≥35 years of age.
Study Design	Cross-sectional, multicenter trial.
Number of Sites	2 sites.
Total Number of Subjects	50 subjects.
Duration of Study	6 months.
Inclusion Criteria	1. Subject must be an outpatient, male or female subjects of any race, 35 years of age or older. 2. Subjects must have no evidence of clinically moderate to severe active acne activity or significant infectious process in the 6 months prior to study initiation. 3. Subjects of all Fitzpatrick skin types are eligible. 4. Subject must be able to follow study instructions and likely to complete all required visits, as assessed by the Investigator. 5. Subject must sign an IRB-approved Informed Consent form, Photographic Release Form, and the Authorization for Use and release of Health and Research Study Information (HIPAA) form prior to any study-related procedures being performed.
Exclusion Criteria	1. Any of the previous facial treatments: a. Any facial filler in the past 2 years b. Prior injection of permanent facial implant 2. Have any skin pathology or condition that could interfere with the evaluation of the face. 3. Be unable to communicate or cooperate with the Investigator due to a language barrier (non-English speaking), poor mental development, or impaired cerebral function. 4. Have evidence of alcohol or drug abuse (Investigator opinion), or history of poor cooperation, non-compliance with medical treatment, or unreliability. 5. Have used an investigation device, biologic or drug in the past 30 days, or be currently participating in an experimental drug, biologic or device trial. 6. Have a condition or be in a situation that, in the Investigator's opinion, may put the subject at significant risk, may confound the study results, or may interfere significantly with the subject's participation in the study. 7. Be an employee (or a relative of an employee) of the Investigator, Sponsor or representative of the Sponsor.
Study Measurements	Subject self-reported quality of life scale
Study Procedures and Assessment Schedule	Eligible subjects will be given a self report questionnaire to complete 1 month after their second or third injection while in the physician's office. A subset of subjects will have baseline and post injection photographs taken.
Statistical Methods	Data will be summarized using descriptive statistics.

1. Background and Rationale

Facial volume loss can substantially impact both self perception of the affected individual and their social/professional interactions and opportunities. Persons who are perceived as more youthful and attractive are rated as nicer, more energetic, healthier, and more likely to be productive than those perceived to be older and unattractive.
The observed facial changes that result from underlying volume loss often produce an older and less attractive appearance. Loss of facial volume often produces a sad, sunken, deflated, dull, tired, and lackluster appearance. These changes can be interpreted as evidence of aging and loss. In addition, some may consciously or subconsciously see them as harbingers of progressive deterioration and decline. Filler correction of localized areas of facial volume loss has been demonstrated to affect positive changes in emotional and functional status by patient self report measures.

2. Current Clinical Study

A concern among some clinicians is the "delayed gratification" aspect of poly L-Lactic Acid. While its efficacy, safety, and duration of benefit are well supported by the literature, it is unique as a biostimulator leading to the gradual onset of tissue augmentation over several months. Many clinicians wonder whether patients will objectively "remember" their baseline appearance and thus be satisfied with their ultimate cosmetic outcome.
The goal of this study is to assess both the short term and longer term (3 months post first injection and 6 months post first injection) satisfaction with facial volume restoration with poly L-Lactic Acid.

Specifically, a patient self report questionnaire, previously utilized in several facial filler studies, will be completed by study participants at 3 months and six months after their initial facial injections to assess the emotional and functional effects produced by pan facial treatment with Poly-L-Lactic Acid. The obtained data will hopefully further enhance our appreciation and understanding of the benefits of facial volume restoration. Insight will hopefully be provided into the benefits of gradual onset of volumization with prolonged duration of improvement.

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Buttressing and clarifying the data on the emotional and functional benefits of facial volume restoration can further "legitimize" treatment with poly L-Lactic Acid as an effective and meaningful medical procedure. Dissemination of data substantiating that volume restoration is more than simply a vanity or cosmetic intervention can serve as a compelling "recruitment tool" for the growing number of "maturing persons" struggling with the deflation and lackluster appearance that accompany the volume loss associated with aging, medications, stress, and illness.

3. Objectives

Objective 1: To assess the emotional and functional improvement produced by pan facial improvement with Poly-L-Lactic Acid

Objective 2: To assess to stability of these affects after treatment

Objective 3: To further substantiate the legitimacy and value of facial volume restoration.

4. Study Design

This is a multi-center study utilizing 2 centers (Yardley Dermatology Associates, 903 Floral Vale Blvd., Yardley PA 19067 and Spokane Dermatology-Werschler Aesthetics, 324 South Sherman Street, Spokane WA 99202. Subjects will be recruited from private practice dermatology offices. Eligible patients must meet the inclusion and exclusion criteria as stated below.

5. Study Population

5.1 Number of Subjects

50 male and/or female subjects 35 years of age or older who meet the protocol's participant eligibility requirements will be enrolled in the study at 2 investigational sites.
Study sites will be selected on the basis of experience in facial volume restoration and anticipated subject enrollment rate, with the objective of completing enrollment within approximately 2 months.

5.2 Inclusion Criteria

1. Subject must be an outpatient, male or female subjects of any race, 35 years of age or older.
2. Subject must have any degree of facial volume loss.
3. Subjects of all Fitzpatrick skin types are eligible.
4. Subject must be able to follow study instructions and likely to complete all required visits, as assessed by the Investigator.
5. Subject must sign an IRB-approved Informed Consent form, Photographic Release Form, and the Authorization for Use and release of Health and Research Study Information (HIPAA) form prior to any study-related procedures being performed.

5.3 Exclusion Criteria

1. Any of the previous facial treatments:
    c. Any facial filler in the past 2 years
    d. Prior injection of permanent facial implant
2. Have any skin pathology or condition that could interfere with the evaluation of the face.
3. Be unable to communicate or cooperate with the Investigator due to a language barrier (non-English speaking), poor mental development, or impaired cerebral function.
4. Have evidence of alcohol or drug abuse (Investigator opinion), or history of poor cooperation, non-compliance with medical treatment, or unreliability.
5. Have used an investigational device, biologic or drug in the past 30 days, or be currently participating in an experimental drug, biologic or device trial.
6. Have a condition or be in a situation that, in the Investigator's opinion, may put the subject at significant risk, may confound the study results, or may interfere significantly with the subject's participation in the study.
7. Be an employee (or a relative of an employee) of the Investigator, Sponsor or representative of the Sponsor.

6. Enrollment

Subjects will have the study explained and will be asked about their willingness to participate, including their willingness to sign an informed consent and a photography release form. To comply with Health Insurance Portability and Accountability Act (HIPAA) requirements, a separate authorization for disclosure or use of protected health information will be signed. After full consent, subjects will be considered enrolled into the study.

7. Informed Consent and Subject Privacy

The purpose and procedures to study participation will be discussed with each potential subject. Prior to any study-related procedures subjects must give their written informed consent. The subject must also give Authorization for Use and Release of Health and Research Study Information (HIPAA), authorization to take identifying clinical photographs for scientific and regulatory use and other written documentation required by local regulations and/or the reviewing IRB prior to any study-related procedures.

8. Study Assessments

Prior to enrollment of any study subjects, the Investigators will be trained in the use of the assessment scale. Subjects will receive training on how to complete the Volume Restoration Quality of Life Scale..

The Sponsor will prepare written procedures on how to perform digital imaging in a standardized fashion.

8.1 Investigator Global Assessment (IGA) of Facial Volume Loss

Grade	Description
0	No visible volume loss
1	Mild volume loss.
2	Moderate volume loss
3	Severe volume loss
4	Very severe volume loss

8.2 Subject Self- Report Quality of Life Instrument

A subject self-report instrument with 35 questions will be distributed to the subject for completion at the study site. This questionnaire is designed to assess the emotional and functional impact of facial acne scarring.

8.3 Photography

Photographs for the study may be taken only at an investigators site as designated by the sponsor. Written training regarding study related photography will be provided during site initiation visits (where applicable).

9. Schedule of Study Activities

Subjects must meet all screening criteria as assessed by subject interview and through examination of facial volume loss. Please refer to the following schedule for additional details:

1. Discuss with each subject his/her willingness to participate in the study and obtain Informed Consent/HIPAA.
2. Inclusion/Exclusion Criteria
3. Document Subject Demographic Information
4. Subject Photography
   a. To be conducted at baseline prior to first injection and 3 month and 6 month post initial injection. Photography instructions to be provided in a separate study document.
5. Facial volume loss assessment by Investigator and subject
   a. Investigator/Subject Facial Volume Loss Global Assessment
6. Subjects will receive 1 vial of poly-L-lactic acid reconstituted in the usual sterile fashion with 7cc of sterile water and 2cc of Lidocaine without epinephrine. The contents of the vial will be injected as deemed appropriate by the certified injector and agreed upon by the study subject.
7. Approximately 4-6 weeks later, a second vial will be reconstituted as above and injected according to the above parameters.
8. Approximately 4-6 weeks later (8-12 weeks after the first injections), subjects will be evaluated and a decision jointly made with the injector regarding whether a third vial is desired and appropriate.
9. Injection sites will be prepared in the usual sterile fashion and sites will have Lidocaine topical application 30-90 minutes before the procedure.
10. All subjects will receive full informed consent and will have time for any questions before procedures are initiated.
11. Explicit post procedure instructions will be provided as per usual protocol.
12. Subjects will be instructed to contact the study site immediately with any concerns after each injection session.
13. QOL and Self-Esteem measures by subject
    a. To be completed 3months and 6 months post initial injection.

10. Early Discontinuation/Withdrawal

It is the right and duty of the Investigator to discontinue a subject's participation when the subject's health or well-being is threatened by continuation in the study. Such subjects should be withdrawn from the study. In the event of premature discontinuation, the Investigator should determine the primary reason for discontinuation. Subjects may voluntarily withdraw from the study at any time without jeopardy to future medical care. For any subject who withdraws from the study the date and reason for withdrawal will be recorded on the CRF.

11. Compliance with Protocol

The Investigator is responsible for compliance with the protocol at the investigational site. A representative of the Sponsor will make contact with the Investigator and his/her research staff to obtain completed CRFs.

12. Study Termination

If conditions arise during the study that indicate that the study or an investigational site should be terminated, the Sponsor, Investigator, Monitor, IRB, and/or regulatory agencies will discuss the situation and take appropriate action after consultation.

Conditions warranting termination of the study or site include, but are not limited to:

- The decision on the part of the Sponsor to suspend or discontinue evaluation, or development of the study.
- Failure of the Investigator to comply with pertinent national or state regulations, IRB-imposed conditions, or protocol requirements;
- Submission of knowingly false information from the Investigator to the Sponsor, IRB, or any regulatory agency.

13. General Statistical Analysis Methods

Relevant subject information i.e. demographics, facial volume restoration questionnaire answers will be collected and analyzed. This data will be summarized using descriptive statistics.

14. Administrative Issues

This protocol will be conducted in accordance with the applicable U.S. Food and Drug Administration (FDA) regulations and guidelines and Good Clinical Practice (GCP), i.e., the International Conference on Harmonization (ICH) Guideline on Good Clinical Practice.

14.1 Protection of Human Subjects

14.1.1 Compliance with Informed Consent Regulations (21 CFR Part 50)

Written informed consent will be obtained from each subject prior to enrollment into the study, i.e., before performing any screening evaluations or questionnaire completion.

14.1.2 Compliance with Institutional Review Board Regulations (21 CFR Part 56)

This study will be conducted in accordance with IRB regulations (U.S. 21 CFR Part 56.103). The Investigator must obtain approval from a properly constituted IRB prior to initiating the study. Yardley Clinical Research Associates is to be notified immediately if the responsible IRB has been disqualified or if proceedings leading to disqualification have begun.

14.1.3 Compliance with the Principles of Good Clinical Practice (ICH E6)

This protocol will be conducted in accordance with the applicable Good Clinical Practice (GCP) regulations and guidelines (ICH E6).

No amendments to the protocol will be implemented without the prior written consent of the Sponsor. Should an amendment be necessary, the reviewing IRB may require review and approval prior to implementation.

14.2 Subject Confidentiality

A report of the results of this study may be published, but the subject's name will not be disclosed in this document. The subject's name may be disclosed to the Sponsor of the study (Yardley Clinical Research Associates), the governing health authorities, or the FDA (U.S. Food and Drug Administration) if they inspect the study records. Appropriate precautions will be taken to maintain confidentiality of medical records and personal information.

14.2.1 Subject Privacy

Written authorization will be obtained from each subject prior to enrollment into the study in accordance with the applicable privacy requirements [e.g., the Health Insurance Portability and Accountability Act Standards for Privacy of Individually Identifiable Health Information ("HIPAA")].

14.3 Required Regulatory Documents

It is the responsibility of the Investigator and study staff to maintain a comprehensive and centralized filing system of all study-related documentation, which is suitable for inspection at any time either by the IRB or FDA . Elements should include:

- Subject files containing the completed case report forms, supporting source documentation and the informed consent, with signatures by the Investigator or sub-Investigators.
- Confidential disclosure agreement with the sponsor.
- Financial disclosure forms for each Investigator or sub-Investigator.
- Study files, containing the following required documentation:
  - Protocol with all amendments
  - Copies of all pre-study documentation and all correspondence to and from the IRB and the sponsor or sponsor representatives
  - An up-to-date curriculum vitae for the principal Investigator.
  - Signed and dated Investigator agreement
  - Assurance that the reviewing IRB complies with the requirements set forth in Title 21 Part 56 of the CFR. The required documentation will consist of the name and address of the IRB and a list of its members, including their titles, occupations, and any institutional affiliations, or a DHHS Assurance number.
  - A copy of the formal written notification regarding approval of the protocol by the IRB.
  - A copy of the IRB approved informed consent form and other adjunctive materials (e.g., advertising) used in the study, including written documentation of IRB approval of these items.
  - In addition to the documents required prior to the study, other documentation may be required during the course of the study.

14.3.1 Source Documents

Individual subject records will be maintained in the Investigator's Source Documents (SDs). Source documentation is generally considered to be the document on which the information or data point was first recorded. SDs may include a subject's medical records, hospital charts, clinic charts, and the Investigator's study files as well as the results of diagnostic tests such as X-rays, laboratory tests, and electrocardiograms. The Investigator's copy of the CRF may also serve as part of the Investigator's source record for a subject's study-related data. The following information should be entered into the subject's medical record:

a. Subject's name
b. Subject's contact information
c. The date that the subject entered the study and the subject number assigned
d. The study title and/or the protocol number of the study and the Sponsor's name (Yardley Dermatology Associates, PC)
e. A statement of the informed consent process and the date that informed consent and HIPAA authorization were obtained.
f. Records of previous and current dermatological treatments and/or therapies
g. Dates of all subject visits
h. The date the subject exited the study, and a notation as to whether the subject completed the study or reason for discontinuation

Study-specific information, such as Investigator and subject effectiveness and safety assessments may be recorded directly on the CRF. With no prior written or electronic record, these data are considered to be source data and will be maintained in the Investigator's study files. Pertinent records related to the study, e.g., the subject's medical chart, will be made available to the Sponsor representative on request with due precaution to protect the privacy of the subject. Personal identifying information (except subject initials) will be redacted on any photocopies of relevant medical records and replaced with the unique Subject Number before submission to the Sponsor. The Investigator will protect the confidentiality of all subjects' records within applicable federal, state and local laws.

14.3.2 Case Report Form (CRF) Completion

The Investigator is responsible for ensuring that data are properly recorded on each subject's CRFs and related documents. The Investigators must sign the protocol signature page and will personally sign where indicated on the respective CRF pages to certify that the observations and findings are recorded on the CRFs correctly and completely. All required data will be recorded on the CRFs for this study, which will be designed and provided by the Sponsor.

All CRF entries must be in ink; black is preferred. An error will be corrected by a single line drawn through it, and the correct data, recorder's initials and correction date will be entered adjacent to the error. All errors must remain legible. Erasure or obliteration of errors on the CRF or other permanent study record is strictly prohibited.

The reason for any missing CRF data will be explained:

a. Not performed or not done = ND
b. Cannot be determined or approximated, unknown = UNK or UN
c. Does not apply, not applicable = NA
d. No data are available = NAV

Copies of the CRF pages will be collected by the Sponsor after review and verification of the completion and accuracy of the study data. As needed, the Investigator will be contacted to clarify illegible or incomplete CRF entries.

14.3.3 Retention of Documentation

Essential documents are any records that demonstrate the compliance of the subject, Investigator, Sponsor, and Monitor with the study protocol, with standards of Good Clinical Practice (GCP), and with all applicable regulatory requirements. Essential documents (including but not limited to study-related correspondence, subject records, subject privacy documentation, records of the distribution and use of all investigational devices, and copies of CRFs should be retained and available for audit by the Sponsor's auditor and regulatory authorities until at least 2 years after completion or termination of the study. It is the responsibility of the Sponsor to inform the Investigator when these documents no longer need to be retained

14.4 Proprietary Information

The information generated during this study is considered to be the property of the Sponsor, and cannot be used in publication without the written consent of the Sponsor.

14.5 Publications

Sponsor-Investigator retains the right to publish study findings in the venue of its choice.

14.6 References

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2. Werschler, WP; Smith, Scott, DO. "Mechanism of Action of Poly-L-Lactic Acid: A Stimulatory Dermal Filler". Supplement to Journal of Drugs in Dermatology, January 2007: Vol 6(1):18-20

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4. Sapijaszko MJA. Dermal Fillers: Ever-Expanding Options For Esthetic Use. Skin Therapy Letter 2007;12(8):4-7

5. LaTrenta GS. The aging face. In: Atlas of Aesthetic Face and Neck Surgery. Philadelphia, Pa: Saunders; 2004:46-66.

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7. Fitzgerald R, Graivier MH, Kane M, Lorenc ZP, Vleggaar D, Werschler WP, Kenkel JM. Update on Facial Aging. Aesthetic Surgery, July/August 2010 30: 11S-24S.

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9. Fried RG. Remember me? Helping patients come face to face with aging. Skin and Aging 2009; Vol. 17, Issue 10, 42-44.

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11. Fried RG. Optimal Facial Rejuvenation: Looking for Help From Above. The Dermatologist 2014 Vol.22(12);18-19.

APPENDIX 1: Facial Volume Restoration Outcome Questionnaire

Site # _____ Subject # _____

Treatment visit 1 date: _____

Treatment visit 2 date: _____

Treatment visit 3 date: _____

Date: _____

Sex: ___ Female ___ Male

Age: ___ 35-45 ___ 45-60 ___ 60-75

City/Country of residence: _____

Number of Poly-L-Lactic Acid treatments: _____

Please circle the number that best describes how you feel. Circling the number one suggests that you believe that the description on the left hand column best describes how you feel. Circling the number 7 suggests that you believe that the description on the right hand column best describes how you feel. Circling number 4 suggests that you feel that there has been no change. Please be honest.

Since my Poly-L-Lactic Acid injection (s), I find that I am in general…

1. Less anxious	1 2 3 4 5 6 7	More anxious
2. More optimistic	1 2 3 4 5 6 7	Less Optimistic
3. More energetic	1 2 3 4 5 6 7	Less energetic
4. Eating more healthy food	1 2 3 4 5 6 7	Eating less healthy food
5. Happier	1 2 3 4 5 6 7	Sadder
6. Exercising more	1 2 3 4 5 6 7	Exercising less
7. Less irritable	1 2 3 4 5 6 7	More irritable
8. More amorous	1 2 3 4 5 6 7	Less amorous
9. More social	1 2 3 4 5 6 7	Less social
10. More productive	1 2 3 4 5 6 7	Less productive
11. More focused	1 2 3 4 5 6 7	Less focused
12. Less tired	1 2 3 4 5 6 7	More tired
13. Less angry	1 2 3 4 5 6 7	More angry
14. More confident	1 2 3 4 5 6 7	Less confident
15. More sexually confident	1 2 3 4 5 6 7	Less sexually confident
16. More assertive	1 2 3 4 5 6 7	Less assertive
17. Less argumentative	1 2 3 4 5 6 7	More argumentative
18. More comfortable with others	1 2 3 4 5 6 7	Less comfortable with others
19. More likely to go out	1 2 3 4 5 6 7	Less likely to go out
20. More involved in community activities	1 2 3 4 5 6 7	Less involved in community activities
21. Doing better at work/school	1 2 3 4 5 6 7	Doing worse at work/school
22. More in control	1 2 3 4 5 6 7	Less in control
23. Taking more medications	1 2 3 4 5 6 7	Taking less medications
24. Less depressed	1 2 3 4 5 6 7	More depressed
25. Seen by others as less stressed	1 2 3 4 5 6 7	Seen by others as more stressed
26. Feeling more attractive	1 2 3 4 5 6 7	Feeling less attractive

27. More relaxed	1 2 3 4 5 6 7	Less relaxed
28. Happier when looking in mirror	1 2 3 4 5 6 7	Less happy looking in mirror
29. Using less cosmetics to hide defects	1 2 3 4 5 6 7	Using more cosmetic to hide defects
30. Happier when my face is touched	1 2 3 4 5 6 7	Less happy when my face is touched
31. My life is better	1 2 3 4 5 6 7	My life is worse
32. Drinking more alcohol	1 2 3 4 5 6 7	Drinking less alcohol
33. Happier with my body	1 2 3 4 5 6 7	Less happy with my body
34. More in control of my eating	1 2 3 4 5 6 7	Less in control of my eating
35. More content	1 2 3 4 5 6 7	Less content

Thank you for your time and honesty.

APPENDIX 2: Investigator Global Assessment (IGA) of Facial Volume Loss

Grade	Description
0	No visible volume loss
1	Mild volume loss.
2	Moderate volume loss
3	Severe volume loss
4	Very severe volume loss

APPENDIX 3: Rosenberg Self-Esteem Scale

Rosenberg Self-Esteem Scale

Circle one response for each of the following ten items.

	Strongly Agree	Agree	Disagree	Strongly Disagree
1. I feel that I am a person of worth, at least on an equal basis with others.	1	2	3	4
2. I feel that I have a number of good qualities.	1	2	3	4
3. All in all, I am inclined to feel that I am a failure.	1	2	3	4
4. I am able to do things as well as most other people.	1	2	3	4
5. I feel I do not have much to be proud of.	1	2	3	4
6. I take a positive attitude toward myself.	1	2	3	4
7. On the whole, I am satisfied with myself.	1	2	3	4
8. I wish I could have more respect for myself.	1	2	3	4
9. I certainly feel useless at times.	1	2	3	4
10. At times, I think I am no good at all.	1	2	3	4

Source: Morris Rosenberg's "Self-Esteem Scale" from pp-325-327 of *Society and Adolescent Self-Identity* 1989 by Morris Rosenberg, Wesleyan University Press.